



We are leading the way in endovascular therapies.

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Washington, DC 20549 THOMSON REUTERS

ev3 is a global leader and best-in-class technology provider for specialists treating a wide range of vascular diseases and disorders. ev3 is committed to the peripheral vascular and neurovascular markets, and the physician specialties that serve them. Our SINGULAR MISSION is to help our customers improve the quality of their patients' lives through the development of innovative endovascular technologies and emerging therapies.

## OUR VALUES

As employees of ev3 we make decisions based on what we believe.

PEOPLE are at the heart of everything we do—from employees to our customers to the patients they serve, we strive to positively impact every life we touch.

Passion is the fuel that drives and motivates us. We believe enthusiasm is both contagious and inspiring.

IDEAS are the cornerstone of innovation and fundamental to our success. We embrace creativity and are in constant pursuit of finding a better way.

QUALITY is everyone's responsibility. We strive to be best-in-class with our people and our products.

INTEGRITY is not optional at ev3. We hold ourselves and those with whom we interact to the highest ethical standards.



DAN LEVANGIE

Chairman of the Board of Directors
ev 3 Inc.

## TO OUR VALUED SHAREHOLDERS, CUSTOMERS, AND EMPLOYEES:

I am pleased to report on the progress of ev3 during 2007.

This was a significant and important year in the development and growth of our company.

We continue to focus our company's expertise and resources on serving the peripheral vascular and neurovascular markets. Fueled by an aging global population and an increase in the incidence of diabetes, heart disease, and high blood pressure, we believe that these two segments will continue to experience considerable growth, reaching a combined worldwide market potential of approximately \$7 billion by the end of 2010.

Our merger with FoxHollow Technologies in October 2007 created a company with an unequaled focus and technological offering for peripheral vascular disease, as well as one of the largest U.S. distribution footprints in peripheral endovascular devices.

We now offer a wide array of products to treat vascular disease in both the peripheral and neurovascular markets, including atherectomy and thrombectomy, PTA balloons, balloonexpandable and self-expanding stents, embolic protection devices, infusion catheters and wires, embolization coils, and liquid embolics. Yet 2007 was not without its challenges. The results of our first quarter of combined ev3 and FoxHollow operations, specifically the sales integration and resulting revenue, were below our expectations. And although the challenges associated with an acquisition of this size have had a temporary impact on our short-term operating results, we have received validation from our physician customers that our strategy of offering a broad portfolio of peripheral vascular solutions and our investment in clinical research can add considerable value to their clinical practice and benefit the patients they treat. We remain confident in the strategic and financial rationale for the merger and believe that it is a key element in advancing our business agenda and delivering profitable growth for our shareholders.

Today, more than ever, we believe that ev3 is well positioned to fulfill our mission of improving the lives of patients with vascular disease through the development of innovative endovascular therapies.

Sales growth across business segments and markets

Net sales for 2007 were \$284.2 million, up 40 percent compared to 2006. Our results, which included \$26.9 million of FoxHollow product sales and research collaboration revenue from the date of the merger, reflected net sales growth in each of our reportable.



"From start to finish, the AXIUM™ DETACHABLE COIL SYSTEM offers the ability to easily and completely fill and pack the aneurysm, regardless of its shape or size. In addition, the proprietary I.D. Instant Detachment System facilitates precise and rapid coil deployment."

Demetrius Lopes, M.D. Director, Endovascular Surgery Rush University Medical Center—Chicago, Illinois

business segments and geographic markets. We also saw increased market penetration of products introduced during the past two years, including our PROTÉGÉO EverFlexO self-expanding stents, OnyxO Liquid Embolic System, and the AXIUM™ Detachable Coil System.

Peripheral vascular net sales increased 43 percent to \$173.8 million over 2006. These results were negatively impacted by greater than anticipated sales force integration challenges and elevated customer inventory levels of SilverHawk<sup>©</sup> products. We believe that the actions we have taken to date—streamlining the sales management structure, bringing management of the company closer to the customer, and focusing the new peripheral organization on selling a complete product portfolio of peripheral vascular solutions—will enable us to overcome these challenges and support our future growth objectives.

Driven by the strong performance of our Onyx Liquid Embolic System, our global launch of the AXIUM embolization coil, and sustained growth in our access and delivery products, net sales in our neurovascular segment increased 28 percent to \$104.4 million over 2006. We also completed our global launch activities for our AXIUM coil and set the stage for anticipated increased market share gains by the AXIUM coil in 2008.

International net sales grew 32 percent to \$107.0 million in 2007 compared to 2006. Led by the strong performance of our direct sales organization and complementary distributor network, this growth was primarily a result of successful new product introductions and increased market penetration of existing peripheral vascular and neurovascular products.

In addition to the sales growth we achieved in 2007, we anticipate realizing approximately \$70 million in expense savings on an annual basis going forward from the merger with FoxHollow. This has helped us establish a cost structure that we believe balances the investment needed to build our business with profitable growth for our shareholders.



SIGNIFICANT ACCOMPLISHMENTS IN EVERY AREA

In 2007, we made important progress in every area of the
company:

- We completed our merger with FoxHollow Technologies, broadening our peripheral vascular product offering to include the SilverHawk Plaque Excision System for use in atherectomy procedures.
- We successfully launched our PROTÉGÉ RX Carotid Stent, additional lengths in our EverFlex family of stents, the Visi-Pro<sup>TM</sup> Balloon Expandable Stent, and our SilverHawk LS-M and MS-M atherectomy products in the U.S. for the peripheral vascular market.
- In our neurovascular business, we launched our AXIUM
   Detachable Coil System and continued to expand the market
   for our Onyx Liquid Embolic System.
- · We established a sales presence in China.
- We completed enrollment in several clinical studies, including our DURABILITY I and PROSPERO European studies
   evaluating the long-term patency and stent durability of our

PROTÉGÉ EverFlex Stent in long, challenging superficial femoral artery (SFA) lesions.

- We received conditional approval and began enrolling patients for our DURABILITY II study in the U.S. with the objective of expanding our PROTÉGÉ EverFlex Stent's indication for use to include treatment of peripheral artery disease in the SFA and proximal popliteal arteries of the leg.
- We were awarded three, three-year contracts by Novation, the health care contracting and services company of VHA Inc. and the University HealthSystem Consortium, covering our peripheral interventional, thrombus management, and neuro interventional products.

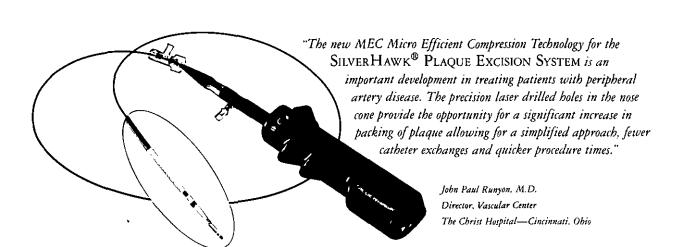
Peripheral. Vascular poised for growth

Our peripheral vascular business offers a comprehensive portfolio

of treatment options—stents, PTA balloons, and atherectomy

systems—for patients with peripheral artery disease.

We are focused on expanding our market position in the peripheral vascular market through our large direct sales organization and on increasing revenues by selling a full product and procedure portfolio of the combined companies.



"Preliminary evaluation of long stents in a challenging patient population showed that treatment with the PROTÉGÉ® EVERFLEX® STENT results in high patency rates and low fracture rates. Additionally, the helical design gives flexibility that cannot be

PROTÉGÉ® Es System is intended. a neoplasms in the and effectiveness

PROTÉGÉ® EverFlex® Self-Expanding Biliary Stent System is intended as a palliative treatment of malignant neoplasms in the biliary tree. WARNING: The safety and effectiveness of this device for use in the vascular system have not been established.

We will continue to invest in developing next-generation atherectomy products such as our Rock Hawk \*\* Plaque Excision System, which was recently cleared for surgical use to treat calcified lesions. We will also continue to support clinical trial initiatives to drive broader product and procedure adoption and bring new products to market.

ADVANCING OUR NEUROVASCULAR LEADERSHIP POSITION

In our neurovascular business, we will continue to focus on the launch of our AXIUM coil, which is now available worldwide.

We are very encouraged by early physician response and believe the unique features of the AXIUM coil—including stretch resistance, progressive wire diameters that maximize aneurysm packing density, improved conformability, and a proprietary instant detachment system—may enable interventionalists to approach even the most challenging anatomy with new capability and confidence.

In Europe, we have begun selectively commercializing our SOLITAIRE<sup>TM</sup> Flow Restoration stent, which we believe could represent a unique advancement in treating ischemic stroke

patients. We are looking forward to initiating our European clinical study for this device in the second half of 2008.

We believe that we can continue to build upon our number two worldwide revenue share position in neuro through the continued market penetration of both the AXIUM coil and the Onyx Liquid Embolic System for the treatment of brain arterio-venous malformations (AVMs).

Driving our International organization and presence We expect significant gains in 2008 from our international business. We anticipate this growth to stem from new product introductions and increased market penetration of peripheral vascular and neurovascular products.

We also are continuing to implement our strategy for our SilverHawk atherectomy products, which includes training physicians, establishing key opinion leaders, conducting European clinical research, and developing specific product and procedure reimbursement strategies to support our international sales efforts.

Clinical validation remains important for our international business, and we expect our foundation work in the DURABILITY I and PROSPERO studies to be followed by critical clinical initiatives in atherectomy that will build upon clinical safety and efficacy to support adoption and reimbursement initiatives worldwide.

Building the clinical foundation for our products

We continue to focus on validating the clinical and competitive
benefits of our technology platforms to drive new and enhanced
products and increase market penetration.

To this end, we have a number of clinical trials underway and others in development. In addition to the DURABILITY I, DURABILITY II, and PROSPERO studies, our clinical agenda for 2008 will include our PROVE-IT trial studying the use of balloon-expandable and self-expanding stents for percutaneous stent treatment in iliac vessels and our U.S. clinical trial for percutaneous removal of calcium using our RockHawk system and the SpiderFX\* Embolic Protection Device.

## SIX KEYS TO A SOLID FUTURE

We will continue to build upon our foundation to drive longterm shareholder value by focusing in 2008 on:

- Increasing procedural penetration across both segments by expanding the distribution channel to endovascular specialists worldwide.
- Improving sales representative utilization and productivity by selling a complete portfolio of peripheral vascular and neurovascular solutions and leveraging our agreement with Novation to gain access to accounts that currently do not use ev3 products.
- Expanding our portfolio of products to treat peripheral vascular and neurovascular disease.
- Driving growth and continuing our expansion in international markets.

- Investing in a broad clinical trial program to further validate
  the scientific underpinnings of our current endovascular
  procedures, to allow for approved expansion into new market
  segments, and to support reimbursement in the U.S. and
  internationally.
- Achieving year-over-year improvement in operating margin, adjusted EPS, and free cash flow.

I would also like to address our recent change in leadership. In April 2008, we named Bob Palmisano as President and Chief Executive Officer of ev3. Recently serving as President and Chief Executive Officer of IntraLase Corp., Bob brings more than 20 years of experience in the pharmaceutical and medical device industries to ev3. He is a proven leader and hands-on operator with the right combination of experience to lead our company through the next phase of our growth and success.

In closing, I would like to thank the entire ev3 worldwide team for its efforts in 2007, including the successful completion of our FoxHollow merger and continued focus on building our core business. As one unified company, we are better equipped than ever to continue our important work of improving the lives of people with vascular disease through the use of our innovative endovascular therapies.

We also want to thank our hospital customers, clinicians, their patients, and our shareholders for their continued support. Driving our business forward and executing according to our plan will continue to be our top priority. We look forward to sharing our progress throughout the year.

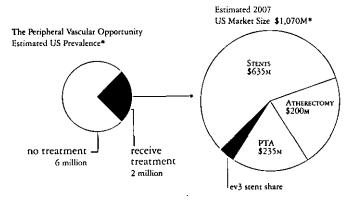
Sincerely,

Dan Levangie

Chairman of the Board of Directors

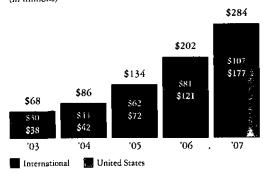
ev3 Inc.

## The US Peripheral Vascular Market

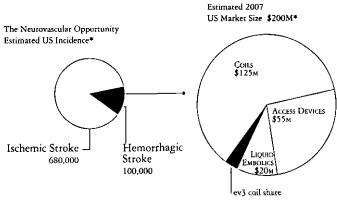


<sup>\*</sup>American Heart Association estimates for Prevalence; Internal estimates for Market Size

Total Net Sales (in millions)

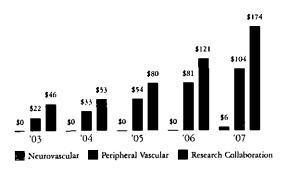


The US Neurovascular Market



<sup>\*</sup>American Heart Association estimates for Incidence; Internal estimates for Market Size

Neurovascular and Peripheral Vascular Net Sales (in millions)



# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# Form 10-K

(Mark	one)
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ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2007

□ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from

to

Commission file number 000-51348

ev3 Inc.

(Exact name of registrant as specified in its charter)

Washington, DC 20549 32-0138874

Received SEC

APR 16 2008

(I.R.S. Employer Identification No.)

55442 (Zip Code)

Delaware

(State or other jurisdiction of incorporation or organization)

9600 54th Avenue North, Suite 100 Plymouth, Minnesota

(Address of principal executive offices)

(763) 398-7000

(Registrant's telephone number, including area code)

Securities registered pursuant to section 12(b) of the Act:

Title of Each Class:

Name of Each Exchange on Which Registered:

Common Stock, par value \$0.01 per share

The NASDAQ Stock Market

Securities registered pursuant to section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES  $\square$  NO  $\square$ 

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES  $\square$  NO  $\square$ 

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☑ NO □

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer 2

Non-accelerated filer (Do not check if a smaller reporting company)  $\square$ 

Smaller reporting company □

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Act). YES  $\square$  NO  $\square$ 

The aggregate market value of the registrant's common stock, excluding outstanding shares beneficially owned by affiliates, computed by reference to the closing sale price at which the common stock was last sold as of June 29, 2007 (the last business day of the registrant's second quarter) as reported by the NASDAQ Global Select Market, was \$435,918,235.

As of March 3, 2008, 105,222,840 shares of common stock of the registrant were outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

Part III of this annual report on Form 10-K incorporates by reference information (to the extent specific sections are referred to in this annual report) from the registrant's proxy statement for its 2008 annual meeting of stockholders.

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This annual report on Form 10-K contains and incorporates by reference not only historical information, but also forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe harbor created by those sections. We refer you to the information under the heading "Part I. Item 1. Business — Forward-Looking Statements."

As used in this report, references to "ev3," the "company," "we," "our" or "us," unless the context otherwise requires, refer to ev3 Inc. and its subsidiaries.

We own or have rights to various trademarks, trade names or service marks, including the following: ev3®, PROTEGE®, EVERFLEX™, PARAMOUNT™ MINI, PRIMUS™, SPIDERX®, SPIDERFX®, X-SIZER®, HELIX™, THE CLOT BUSTER®, GOOSE NECK®, VISI-PRO™, NITREX®, NEXUS™, ONYX®, MORPHEUS™, SOLO™, ECHELON™, ULTRAFLOW™, MARATHON™, HYPERFORM™, HYPERGLIDE™, MIRAGE™, AXIUM™, SOLITAIRE™, SILVERSPEED®, X-PEDIUM™, X-CELERATOR™, FOXHOLLOW®, SILVERHAWK®, RINSPIRATOR®, NIGHTHAWK™, and ROCKHAWK™. The trademarks PLETAL®, PLAVIX®, SAILOR™ Plus, SUBMARINE® Plus, ADMIRAL XTREME™, AMPHIRION®, the DIVER® CE, and ACCULINK® referred to in this annual report on Form 10-K are the registered trademarks of others.

#### PART I

#### ITEM 1. BUSINESS

## Company Overview

ev3 Inc., a Delaware corporation founded in 2000 and headquartered in Plymouth, Minnesota, is a leading global medical device company focused on catheter-based technologies for the endovascular treatment of vascular diseases and disorders. Our name signifies our commitment to, and engagement in, the peripheral vascular and neurovascular markets and the physician specialties that serve them.

We are focused on emerging and under-innovated opportunities which treat peripheral and neurovascular patients around the world, a strategy that we believe is uncommon in the medical device industry. We believe this unique approach allows us to compete with smaller companies that have narrow product lines and lack an international sales force and infrastructure, yet also compete with larger companies that do not have our focus and agility. Within the endovascular market, we have focused our business strategy efforts on the peripheral vascular and neurovascular markets, which we believe offer high growth potential with fewer entrenched competitors.

The competitive strengths that have been responsible for our past success and the strategies that we believe will drive our future growth include:

- · targeting under-innovated and emerging markets;
- · leveraging our products across major endovascular sub-markets;
- investing in clinical research to demonstrate the benefits of our products;
- expanding our business through product innovation and strategic acquisitions;
- · driving our global organization and presence; and
- · leading our business by an experienced management team.

In October 2007, we completed our acquisition of FoxHollow Technologies, Inc. creating a combined company that we believe possesses one of the largest U.S. distribution footprints in peripheral and neurovascular devices with one of the broadest and most technologically advanced product offerings. Our product portfolio includes a broad spectrum of over 100 products consisting of over 1,000 stock keeping units (SKUs) to treat vascular disease in both the peripheral and neurovascular markets, including stents, atherectomy and thrombectomy products, percutaneous transluminal angioplasty, or PTA balloons, embolic protection devices, infusion catheters/wires, embolic coils and liquid embolics.

Our customers include a broad cross-section of physicians, including radiologists, neuroradiologists, vascular surgeons, neuro surgeons, other endovascular specialists and cardiologists. We sell our products in more than 60 countries through a direct sales force in the United States, Canada, Europe and other countries and distributors in selected other international markets. We have also entered into two distribution arrangements for the sale of some of our products on a non-exclusive basis in the United States and Canada. As of December 31, 2007, our direct sales organization consisted of approximately 350 sales professionals, including 246 direct sales representatives selling our peripheral vascular products, 44 direct sales representatives selling our neurovascular products and 60 direct sales representatives selling both. Since our acquisition of FoxHollow, we have spent considerable time and resources integrating our two operations, including in particular, our sales force, and training our combined sales force on our combined product offering and cross-selling opportunities.

We have organized our company into two business segments: peripheral vascular and neurovascular. We manage our business and report our operations internally and externally on this basis. Our peripheral vascular segment, which was formerly referred to as our cardio peripheral segment, includes products that are used primarily in peripheral vascular procedures by radiologists, vascular surgeons and cardiologists and in targeted cardiovascular procedures. Our neurovascular segment contains products that are used primarily by

neuroradiologists and neuro surgeons. During fiscal 2007 and fiscal 2006, these segments generated net sales of \$284.2 million and \$202.4 million, respectively. Our fiscal 2007 net sales include \$20.9 million of net sales from FoxHollow products and \$6.0 million from research collaboration activities during fourth quarter 2007.

The following represents net sales (in thousands) by our two business segments and revenues from our research collaboration with Merck & Co. Inc. as well as by geography during the periods indicated:

	. For the Year Ended December 31,		Percent	For the Year Ended December 31,		Percent
Net Sales by Segment	2007	2006	Change	2006	2005	Change
Peripheral vascular	\$173,775	\$121,104	43.5%	\$121,104	\$ 79,881	51.6%
Neurovascular	104,451	81,334	28.4%	81,334	53,815	51.1%
Research collaboration	5,957		100.0%			NM
Total	<u>\$284,183</u>	<u>\$202,438</u>	40.4%	<u>\$202,438</u>	<u>\$133,696</u>	51.4%
•		ear Ended ber 31,	Percent		ear Ended ber 31,	Percent
Net Sales by Geography	2007	2006	Change	2006	2005	Change
United States	\$177,198	\$121,180	46.2%	\$121,180	\$ 71,848	68.7%
International	106,985	81,258	31.7%	81,258	61,848	31.4%
Total	\$284,183	\$202,438	40.4%	\$202,438	\$133,696	51.4%

For additional financial information regarding each of our segments and our foreign operations, see Note 20 to our consolidated financial statements.

#### The Endovascular Market

Vascular disease can involve either an artery or a vein, and is generally manifested as an occlusion (closure) or rupture of a blood vessel. We estimate that vascular disease affects nearly 92 million people in the United States and more than one billion people worldwide, and is the leading cause of death in the world. It may occur in any part of the body, and is a progressive, pathological condition that leads most often to blood vessel narrowing and obstruction, but can also lead to blood vessel wall weakening and rupture. Vascular disease can occur in the blood vessels of every organ and anatomic area of the body, and can cause a range of conditions including pain, functional impairment, amputation and death.

When the treatment for vascular disease is performed from within a vessel, it is referred to as an endovascular procedure. Endovascular procedures are a minimally invasive means of treating the two major problems that can develop within blood vessels: an occlusion, or stenosis, where the vessel is blocked or narrowed, and an aneurysm, or focal expansion of the vessel wall. Endovascular procedures are performed by accessing an easily accessible artery to reach an occlusion or aneurysm and frequently do not require general anesthesia. During most endovascular procedures, a catheter is placed into the femoral artery in the groin. X-ray imaging or fluoroscopy is used to help the physician advance the catheter to the area to be treated. Endovascular procedures are less invasive and require a smaller incision than conventional, open surgery and we believe have a number of distinct benefits over surgery, including:

- the use of local or regional anesthesia frequently instead of general anesthesia;
- · reduced patient discomfort and shorter recovery times;
- · the reduced need for blood products and transfusions;
- · shorter hospital stays for recovery;
- · lower risks of patient complications related to procedures; and
- potentially lower costs.

In 2007, we believe that there were more than 12,000 interventional radiologists, neuroradiologists, vascular surgeons, neuro surgeons and cardiologists in the United States who were trained in endovascular techniques.

The endovascular device markets which we serve are conventionally divided into three specialties based on anatomic location. We principally focus and serve the peripheral vascular and neurovascular markets.

- Peripheral vascular market includes products used to treat arterial and venous disease in the legs,
  pelvis, neck, kidney and any other vascular anatomy other than that in the brain or the heart. According
  to the American Heart Association, or AHA, more than eight million people in the United States have
  peripheral arterial disease. We estimate that more than 100 million people worldwide are affected by
  peripheral arterial disease.
- Neurovascular market includes products used to treat vascular disease and disorders in the brain, including arterio-venous malformations, or AVMs, and strokes caused by either vascular occlusion (ischemic) or rupture (hemorrhagic). The World Health Organization, or WHO, estimates that there are approximately 15 million cases of stroke worldwide each year. Of these, the WHO estimates that five million people die from the stroke and an additional five million are left with a permanent disability.
- Cardiovascular market includes products used to treat coronary artery disease, atrial fibrillation and
  other disorders in the heart and adjacent vessels. The AHA estimates that,81 million people in the
  United States have cardiovascular disease. We estimate that more than 850 million people worldwide
  are affected by cardiovascular disease.

## Our Peripheral Vascular Markets

Our primary focus is developing and commercializing products for selected peripheral vascular markets. Some of these products may also be used in certain cardiovascular markets. We refer to the combination of these selected opportunities as our peripheral vascular markets.

## Peripheral Vascular Disease

Peripheral vascular disease is characterized by the narrowing or total occlusion of blood vessels outside of the heart or brain and can cause conditions including pain, loss of function, amputation and death. Mortality from peripheral vascular disease can occur as a result of stroke, kidney failure or diabetes related vascular complications. The most common type of peripheral vascular disease is peripheral artery disease, which is often used interchangeably with the term peripheral vascular disease, although technically a subset of peripheral vascular disease.

A common cause of peripheral artery disease is atherosclerosis, or "hardening of the arteries." Atherosclerosis is a complex, progressive and degenerative condition resulting from the build-up of cholesterol and other obstructive materials, known as plaque, on the walls of the arteries. The accumulation of plaque narrows the interior or lumen of arteries, thereby reducing blood flow. In addition, plaque may rupture and trigger the release of a blood clot that can further narrow or block an artery.

Plaque occurs in the arteries in several different forms and may be located in many different anatomies throughout the arterial system. Plaque varies in composition, with portions that are hard and brittle, referred to as calcified plaque, and other portions that are fatty or fibrous. Plaque lesions can be long or short, focused or diffuse and can be present in all types of arteries, including straight or curved arteries of varying diameters. Atherosclerosis in arteries outside of the heart and brain causes peripheral artery disease.

Peripheral artery disease is most common in the arteries of the pelvis and legs. Occlusive disease of the iliac arteries, the main vessels descending through the pelvis, is a peripheral artery disease that affects the flow of blood to the legs. Patients with this condition often experience leg pain and numbness or tingling. Restoring the flow of blood in these occluded vessels is essential to maintaining leg function and avoiding complications such as significantly reduced mobility and/or gangrene, which in severe cases can lead to amputation.

Other types of peripheral artery disease involve arteries in the legs, including the superficial femoral artery, or SFA. The legs receive their supply of blood through the femoral arteries, which originate at the groin. The SFA extends from the iliac arteries in the upper thigh down the leg to the knee. At the knee, the SFA becomes the popliteal artery, which branches into arteries that supply blood to the lower leg and foot. Arteries above the knee are generally long, straight and relatively wide although subjected to extreme torsion and compression, while arteries below the knee are shorter and branch into arteries that are progressively smaller in diameter.

Plaque build-up in the pelvic and leg arteries reduces blood flow to the surrounding tissue, causing claudication, the most common early symptom of peripheral artery disease. Claudication refers to pain, cramping or tiredness in the leg or hip muscles while walking. Symptoms may progress to include numbness, tingling or weakness in the leg and, in severe cases, burning or aching pain in the foot or toes while resting. Restoring the flow of blood in these occluded arteries and vessels is essential to maintaining leg function or quality of life and avoiding complications such as gangrene, which in severe cases can lead to amputation.

As peripheral artery disease progresses, additional signs and symptoms occur, including loss of hair on the legs, cooling or color changes in the skin of the legs or feet, and sores on the legs and feet that do not heal. If untreated, peripheral artery disease may lead to critical limb ischemia, or CLI, a condition in which the limb does not receive enough oxygenated blood being delivered to the limb to keep the tissue alive. As reported in *Endovascular Today* in February 2004, up to 30% of the people diagnosed with peripheral artery disease suffer from CLI. If untreated, CLI often leads to large non-healing ulcers, infections, gangrene and eventually limb amputation or death.

The carotid arteries are another common site of peripheral artery disease, affecting an estimated 1.5 million people in the United States alone. Carotid arteries are located on each side of the neck and provide the primary blood supply to the brain. In carotid artery disease, plaque accumulates in the artery walls, narrowing the artery and disrupting the blood supply. This disruption in blood supply, together with plaque debris breaking off the artery walls and traveling to the brain, are the primary causes of stroke.

While peripheral vascular disease is most common in the arterial side where arteries carry oxygenated blood to various organs, it can also occur on the venous side where veins carry blood back to the heart and lungs. Peripheral venous disease is a general term for damage, defects or blockages in the peripheral veins. Like peripheral artery disease, it can occur almost anywhere in the body but is most often found in the arms and legs. The most common form of peripheral venous disease is the formation of blood clots that block the flow of blood in the vessel. Clots that occur in veins close to the surface of the skin are referred to as superficial venous thrombophlebitis, while clotting of veins deep within the body are called deep vein thrombosis. Treatment options for blood clots in the veins are similar to those used to treat clots in arteries.

## Peripheral Vascular Market

According to the AHA, peripheral vascular disease, including peripheral artery disease, affects approximately 8 million people in the United States. Primary risk factors associated with peripheral vascular disease are diabetes and smoking. Other significant risk factors include advanced age, high cholesterol, high blood pressure, obesity and physical inactivity. A family history of cardiovascular disease may also put individuals at higher risk for peripheral vascular disease. According to a study in the *Journal of American Geriatric Society* and a study in the *Cardiology Review*, greater than 60% of people with peripheral arterial disease also suffer from coronary artery disease.

Peripheral vascular disease becomes more common with age and, according to the AHA, affects up to 12% to 20% of the U.S. population 65 and older. Those with diabetes or who are obese are at increased risk of peripheral vascular disease. The Centers for Disease Control estimates that in 2005, there were almost 21 million U.S. adults with diabetes, with approximately 1.5 million new cases of diabetes diagnosed each year. According to the AHA, there were over 67 million obese adults in the United States in 2005. These demographic trends are continuing to contribute to an increase in the prevalence of peripheral vascular disease.

Of the sizeable U.S. peripheral arterial disease population today, only approximately 2 million people are undergoing treatment with the disease, according to the AHA. Underdiagnosis is due in large part to the fact that over one-half of the peripheral vascular disease population does not display classic symptoms of the disease. In addition, others dismiss their symptoms as part of the normal aging process or attribute them to another cause.

Over the next several years, we expect to see continued growth in the peripheral vascular disease patient population, driven by three specific trends: growing prevalence of the disease, increased diagnosis rate and an almost double-digit growth rate in the use of endovascular treatments for infrainguinal peripheral artery disease. While today only approximately 25% of patients with peripheral vascular disease are diagnosed, we believe that the following factors are contributing to a growing diagnosed peripheral vascular disease patient population:

- Increased Awareness. Recent emphasis on peripheral vascular disease education from medical associations, insurance companies and online medical communities, as well as publication in medical journals, is increasing public and physician awareness of peripheral vascular disease risk factors, symptoms and treatment options. The "Legs for Life" campaign screens more than 40,000 people for peripheral vascular disease each year, of which nearly 29% are at moderate to high risk of lower extremity peripheral vascular disease. The American Diabetes Association, or ADA, recommends that all diabetics over the age of 50 be screened for peripheral vascular disease.
- Evolving Physician Practice Patterns. Given that many patients with coronary artery disease also have peripheral vascular disease, we believe that interventional cardiologists and vascular surgeons are increasingly screening patients for both diseases. As a consequence, we believe that physicians are diagnosing more cases of peripheral vascular disease. In addition, heightened awareness of peripheral vascular disease, its symptoms and treatment options is leading to increased referrals from general practitioners, podiatrists who treat patients with pain and lesions in the feet that may be caused by peripheral vascular disease, and nephrologists, diabetologists and endocrinologists, who treat diabetics often experiencing complications resulting from peripheral vascular disease.
- Increased Peripheral Vascular Disease Screening. Studies and medical articles have advocated increased peripheral vascular disease screening by primary care physicians using an ankle-brachial index, or ABI, a simple technique that compares blood pressure in a patient's foot to blood pressure in the patient's arm to determine how well blood is flowing to the foot. In addition to the ABI, physicians are increasingly using established techniques, such as angiography and ultrasound, to either diagnose or confirm diagnosis of peripheral vascular disease.

## Peripheral Vascular Disease Treatment Options

Peripheral vascular disease is treated depending upon the severity of the disease with either non-invasive management, including lifestyle changes and/or drug treatment, for mild to moderate peripheral vascular disease, or minimally invasive endovascular procedures or surgery for more severe peripheral vascular disease.

Non-Invasive Management. For some patients, lifestyle changes and/or drug treatment may slow or reverse the progression of peripheral vascular disease. Lifestyle changes include improving diet, exercising regularly and quitting smoking. Although these adjustments can be effective, many people are unable to maintain this new lifestyle. In addition to lifestyle changes, physicians often prescribe medications that increase blood flow but do not treat the underlying obstruction. Pletal, a commonly prescribed medication for claudication, should not be taken if the patient also has heart disease, which often exists in peripheral vascular disease patients. In addition, physicians often prescribe cholesterol-lowering drugs and drugs for high blood pressure. Patients generally need to take the prescribed drugs for the rest of their lives. According to the American Academy of Family Physicians, 20% to 30% of patients who are non-invasively managed for claudication develop more severe symptoms that require intervention.

Minimally Invasive Endovascular Procedures. Minimally invasive endovascular procedures for the treatment of peripheral vascular disease consist primarily of angioplasty, stenting and atherectomy, and to a

lesser extent, other procedures, such as stents, angioplasty and atherectomy combined with embolic protection devices, laser therapy, drug-eluting stents and vascular cryotherapy. In angioplasty, a catheter with a balloon tip is inserted into the blocked or narrowed part of the artery over a previously positioned guidewire that directs the catheter to the affected area. The balloon is then inflated to compress the plaque and to stretch the artery wall, thereby enlarging, or dilating, the opening of the vessel and restoring blood flow. Stenting is often performed in tandem with angioplasty. Stents are tubular mesh devices typically consisting of interconnected metal struts, which are inserted inside the artery to act as scaffolding in order to hold the vessel open. Atherectomy is a procedure that mechanically removes plaque and other debris that can block arteries throughout the body. During an atherectomy, a physician clears a clogged artery by cutting or shaving the plaque that is blocking a blood vessel. Other interventional treatments for peripheral vascular disease include:

- Stents, angioplasty and atherectomy combined with embolic protection systems, which protect against plaque and debris from traveling downstream, blocking off the vessel and disrupting blood flow;
- laser therapy, which uses a laser to reduce plaque to relatively small particles;
- drug-eluting stents, where a stent is coated with a slow-to-moderate release drug formulation intended to reduce restenosis;
- drug-coated balloons, where an angioplasty balloon is coated with a drug formulation intended to reduce restenosis; and
- vascular cryotherapy, where an angioplasty balloon is inflated with nitrous oxide in an attempt to reduce inflammation caused by treatment of the lesion.

We estimate that in 2007 over 1.2 million endovascular procedures to treat peripheral vascular disease were performed in the United States.

Surgical Procedures. Surgery is used when non-invasive management or minimally invasive endovascular procedures have failed or if the patient is diagnosed when the peripheral vascular disease has progressed to an advanced state. The three main types of surgical procedures include bypass surgery, endarterectomy and amputation.

In bypass surgery, the surgeon reroutes blood around a lesion using a vessel from another part of the body or a tube made of synthetic fabric. Bypass surgery is not advisable for some patients because of the inherent risks of surgery, the symptoms are not deemed to be critical enough to warrant such an intervention, or the existence of other diseases. Bypass surgery has a high risk of procedure-related complications from blood loss, post-procedural infection or reaction to general anesthesia and may require patients to remain hospitalized for several days. Despite these limitations, bypass surgery below the knee remains the most widely practiced method of improving blood flow to a threatened limb and accounts for 75% of all leg procedures in patients with diabetes, according to the ADA.

Endarterectomy involves the surgical removal of plaque. While endarterectomy is sometimes used, the procedure is highly invasive and subjects the patient to the same procedural risks and complications as bypass surgery. Endarterectomy is rarely used below the knee because the arteries below the knee are generally too small to accommodate the procedure.

If CLI progresses to an advanced state, physicians may amputate all or a portion of the limb. According to the ADA Consensus Statement, within six months of the onset of CLI, 30% of patients require amputation. The ADA Consensus Statement also notes that approximately one-half of all patients with CLI in one leg will also develop it in the other leg. We believe peripheral vascular disease accounts for 82% of all such amputations in the United States. It is estimated that there are over 135,000 lower extremity amputations each year in the United States alone, many of which we believe could be treated with endovascular procedures.

## Our Peripheral Vascular Product Portfolio

Our peripheral vascular product portfolio includes products for peripheral vascular procedures which, in some instances, may also be used for selected cardiovascular procedures. Our strategy is to provide a broad

portfolio of products for the peripheral vascular market that includes devices used in frequently performed procedures and also innovative devices for use in emerging therapies. We opportunistically pursue selected cardiovascular markets where some of these products can be used by our cardiologist customers. We do not compete in cardiovascular markets in which several large companies are firmly entrenched, such as coronary stents. The increase in the breadth of our portfolio of peripheral vascular devices has significantly expanded our participation in the peripheral markets over the last couple of years. Our peripheral vascular product portfolio, which was recently expanded with our acquisition of FoxHollow, includes stents, embolic protection devices, carotid stenting solutions, atherectomy and thrombectomy products, PTA balloons and infusion catheters/wires.

#### Stents

Although our stents, like some of our competitors' stents, have been cleared by the FDA for the palliative treatment of malignant neoplasms in the biliary tree, they are used by physicians not only in the biliary duct, which transports bile from the liver and gall bladder to the small intestines, but also "off label" in various other locations in the body, including renal arteries, which transport blood from the aorta to the kidneys; iliac, femoral and popliteal arteries, which are major arteries in the legs and subclavian arteries, which are major vessels of the upper body, originating at the aortic arch. We are currently conducting our DURABILITY II study in the U.S. with the objective of expanding our Protégé EverFlex Self-Expanding Stent's indication for use to include treatment of peripheral artery disease in the superficial femoral and proximal popliteal arteries of the leg. Additionally, we have received conditional approval for our PROVE-IT study in the U.S., which will study the use of both the Protégé EverFlex Self-Expanding Stent and the Visi-Pro Balloon Expandable Stent in iliac arteries. We believe that our portfolio of self-expanding stents is differentiated from our competitors' offerings due to their fracture resistance, flexibility and lengths, and that both our self-expanding and balloon expandable stent platforms provide advanced radiopacity (visibility under fluoroscopy), placement accuracy, deliverability and strong clinical performance.

Protégé EverFlex, Protégé GPS and Protégé GPS BIGGS. Our self-expanding stent portfolio includes our Protégé EverFlex Self-Expanding Stent and our Protégé GPS Self-Expanding Stent, all of which are "shape memory" Nitinol stents that expand to a predetermined diameter upon deployment. Nitinol is a highly flexible metal with shape retention and fatigue resistance properties. We offer a number of sizes of the EverFlex and Protégé GPS stents. The EverFlex stent has enhanced flexibility and resistance to fractures, which we believe provides superior performance in vessels that are subjected to repeated flexing and bending. Designed specifically for use in the superficial femoral artery where peripheral artery disease is often present, the EverFlex stent encompasses a unique spiral cell geometry constructed to withstand the extreme movement of the SFA. Although not a substitute for clinical performance, our internal bench testing has provided us with data suggesting that our EverFlex stent may be up to five to 10 times more durable than stents offered by our competitors. We believe the design of our EverFlex stents is unique in that it features:

- Spiral cell interconnections that greatly enhance flexibility;
- New wave peak structure that more efficiently distributes stress and resists compression; and
- Longer lengths (up to 200 mm and all 6 French compatible), which minimize the need for overlapping stents when treating long lesions.

We offer our customers a guarantee, subject to certain terms and conditions, that our EverFlex stent will remain fracture-free within two years of implantation. Our EverFlex stent was designated as "one of the most significant new product launches in the peripheral stent and stent graft industry" earning us the 2006 Frost & Sullivan Product Innovation Award. We are also the first company to study the use of single stent placement in long lesions, which we believe may lead to reduced restenosis.

ParaMount Mini, PRIMUS and Visi-Pro Balloon Expandable Stents. Our balloon expandable stent portfolio includes stents that incorporate embedded tantalum markers to provide superior visualization under fluoroscopy, allowing the physician to quickly confirm the correct placement. The inclusion of markers is a unique feature in the balloon expandable stent market. We plan to evaluate in our PROVE-IT study the use of

both the Protégé EverFlex Self-Expanding Stent and the Visi-Pro Balloon Expandable Stent in iliac arteries. To our knowledge, this will be the first study of its kind, which evaluates the use of two different stent platforms in one study.

#### **Embolic Protection Products**

During peripheral vascular and cardiovascular procedures, plaque and debris may dislodge or embolize, potentially blocking blood flow and damaging distal tissue. Embolic protection devices are intended to trap plaque and debris from traveling downstream, blocking off the vessel and disrupting blood flow.

SpiderFX and SpiderRX Embolic Protection Devices. The SpiderFX family of embolic protection devices are low-profile devices featuring a unique braided Nitinol embolic filter compatible with most guidewires on the market. Filter-based embolic protection devices allow blood to continue flowing in the artery while the filter traps the debris, minimizing downstream tissue damage and improving clinical outcomes. We believe that the SpiderFX family has a significant competitive advantage because it permits physicians to use their guidewire of choice, allowing improved durability and a more efficient procedure. We believe the SpiderFX also exhibits superior trackability, enhanced visibility and excellent stability.

The SpiderFX is indicated for use as a guidewire and embolic protection system to contain and remove embolic material, such as thrombus or debris, while performing angioplasty and stenting procedures in carotid arteries. It acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts. We are planning a clinical study to evaluate the safety and effectiveness of the RockHawk Plaque Excision System and the SpiderFX for capture, containment and removal of excised plaque and embolic debris during endovascular treatment of moderate to severely calcified peripheral arterial disease in the superficial femoral and/or popliteal arteries. This study, if successful, should support approval for a combined RockHawk and SpiderFX system, thereby expanding the indication of the SpiderFX into the periphery. The SpiderFX is currently indicated for general vascular use outside the United States.

### Carotid Stenting Solutions

Carotid artery stenting represents an emerging minimally invasive treatment option for carotid artery disease. We believe it has the opportunity to become a significant alternative to carotid endarterectomy, where a surgeon accesses the blocked carotid artery though an incision in the neck, and then surgically removes the plaque. It is estimated that 160,000 patients each year in the United States undergo a carotid endarterectomy, which typically requires hospitalization for one to two days. Endovascular techniques using stents and embolic protection systems, which protect against plaque and debris from traveling downstream, blocking off the vessel and disrupting blood flow, have been developed and are in an early stage of adoption. The use of a stent with an embolic protection system avoids open surgery and we believe will increase the number of patients being treated. In 2005, the Centers for Medicare & Medicaid Services, or CMS, expanded coverage of percutaneous transluminal angioplasty of the carotid artery concurrent with stent placement outside of trial settings for patients who are at high risk for carotid endarterectomy in certain circumstances. Coverage is limited to procedures at CMS-approved facilities performed using FDA-approved carotid artery stenting, or CAS, systems and embolic protection devices, which has limited the CAS near-term market potential.

Our carotid stenting product offering (Protégé RX straight and tapered stents used together with our SpideRX and SpiderFX embolic protection devices) are available in the United States, Europe and certain other countries. In support of our FDA pre-market approval submission, we conducted the CREATE Pivotal clinical trial, which was designed to evaluate the use of our carotid stenting technology in patients who are high-risk candidates for carotid endarterectomy. We also have received FDA 510(k) clearance of our SpiderFX embolic protection device for use in carotid artery stenting in conjunction with the Guidant RX ACCULINK stent. We are currently conducting the CREATE Post Approval Study with the objective of further studying the Protégé GPS and Protégé RX Carotid Stent Systems and SpiderFX in the treatment of carotid artery disease in subjects at high risk for complications during surgical treatment of carotid artery disease.

### Atherectomy Products

As a result of our acquisition of FoxHollow, we offer atherectomy products, which are designed to remove plaque from artery walls in order to re-establish blood flow. Unlike most treatments for peripheral artery disease that leave the plaque in the artery, atherectomy products are designed to remove the plaque from artery walls.

SilverHawk Plaque Excision System. The SilverHawk Plaque Excision System is a minimally invasive, catheter system that treats peripheral artery disease by removing plaque in order to reopen narrowed or blocked arteries. The SilverHawk uses a tiny rotating blade to shave away plaque from inside the artery. As it is excised, the plaque collects in a reservoir nosecone located at the tip of the device and then is removed from the patient. The SilverHawk is capable of removing significant amounts of plaque without overstretching the artery, which could lead to dissection or perforation. Plaque excision has helped alleviate severe leg pain for thousands of patients and in many cases has successfully saved the legs of patients who were scheduled for limb amputation after other peripheral interventions had failed.

The SilverHawk provides a treatment approach for peripheral artery disease that we believe offers significant benefits, including:

- Safety. The SilverHawk is designed not to stretch or damage the artery walls, which can lead to dissection or perforation of the artery. We believe that the safety of the SilverHawk, measured by low rates of perforation and dissection, is supported by results from the treatment of 1,517 lesions in 728 patients recorded in our TALON registry. In data published in the Journal of Endovascular Therapy in 2006, less than 5% and 1% of these lesions treated post-SilverHawk had dissections and perforations, respectively. The SilverHawk procedure is minimally-invasive and typically performed under local anesthesia. Therefore, it does not have many of the risks associated with more invasive surgeries and general anesthesia. To date, we have not conducted studies designed to directly compare the safety of the SilverHawk against alternative procedures, such as angioplasty, stenting or bypass grafting.
- Efficacy. Unlike most treatments for peripheral artery disease that leave plaque behind in the artery, the SilverHawk removes plaque. The SilverHawk has removed over 700 milligrams of plaque in a single procedure, with an average of approximately 100 milligrams of plaque per procedure. We believe that excising plaque without causing stretch injury to the artery wall may minimize restenosis and the need for reintervention. We also believe that the efficacy of the SilverHawk, measured by low 12 month reintervention rates is supported by the results of three single site studies as well as our TALON registry. In order to further evaluate the long term safety and efficacy data of the SilverHawk during endovascular treatment of peripheral arterial disease in femoropopliteal arteries, we are planning to conduct a prospective, multi-center, non-randomized, single-arm study to compare SilverHawk to performance goals of PTA in the treatment of atherosclerotic femoropopliteal arteries. The primary effectiveness endpoint is expected to be primary patency at one year as defined by duplex ultrasound peak velocity ratio. Additionally, we intend to capture primary safety of Major Adverse Event rate at 30 days. We expect to start this trial by the third quarter of 2008.
- Treats Difficult to Treat Lesions. The SilverHawk enables physicians to remove plaque from long, bifurcated and difficult to treat lesions in a wide variety of locations, including arteries behind and below the knee and in the foot. Approximately one-third of SilverHawk procedures to date have been performed below the knee, an area where lesions have traditionally gone untreated until they require bypass surgery or amputation. Certain treatment locations, such as arteries below the knee or in the foot, are not suited for physicians with limited experience using the device.
- Utilizes Familiar Techniques. The SilverHawk procedure employs techniques similar to those used in
  angioplasty, which are familiar to the approximately 12,000 interventional cardiologists, vascular
  surgeons and interventional radiologists in the United States who are generally trained in endovascular
  techniques. This significantly increases the number of physicians who are able to perform the procedure
  compared to surgical alternatives that must be performed by highly-trained vascular surgeons. In
  addition, the SilverHawk was designed to be easy to use. The SilverHawk operates with one switch that

controls all device functionality, and has a unique torque shaft designed for a one-to-one correlation between the handle and the tip, providing physicians with precise control of the position of the cutting blade. We continue to focus on providing further enhancements to the SilverHawk as part of our research and development efforts.

- Cost and Time Efficient. A single SilverHawk device can be used to treat multiple and long lesions
  where more than one stent might otherwise be required. Compared to surgical alternatives, the
  SilverHawk procedure reduces cost by allowing physicians to treat patients in a catheterization lab
  instead of an operating room, decreasing the length of hospitalization and reducing complications.
- Allows for Follow-Up Treatment Options. Physicians can, and sometimes do, use adjunctive
  angioplasty and occasionally stenting during a SilverHawk procedure. When the SilverHawk procedure
  is performed without stenting, which we estimate is greater than 90% of the time, increased future
  treatment options remain available in the event that restenosis does occur and reintervention is required
  as there is no metal left behind post procedure, as is the case with stenting.
- Captures and Removes Plaque. The patient and the physician get immediate feedback by seeing the volume of plaque removed, visibly reinforcing the benefits of the procedure. In two on-going studies, conducted in partnership with Merck & Co., Inc., removed plaque is collected and is currently being researched to identify markers of atherosclerotic disease.

In the United States, the SilverHawk is approved for use in the peripheral vasculature. This means that our product may not be marketed in the United States for use in the heart, brain or in specific peripheral anatomy without additional clearances from the FDA. Use of the SilverHawk in the coronary arteries has led to serious adverse events, including perforations, emergency bypass surgery, stroke, heart attack and patient death. In the United States, the SilverHawk is contraindicated, and should therefore not be used, for in-stent restenosis and for use in the carotid, iliac and renal arteries.

The SilverHawk family includes 15 different catheters, which enable the treatment of both calcified and non-calcified lesions of any length, pending the specific device indication. The catheters vary in diameter to treat a wide range of peripheral vessel sizes. The devices also vary in tip length to accommodate lesions with heavier or lighter plaque burden.

We recently announced the U.S. launch of our most recent additions to the SilverHawk family of products: the SilverHawk LS-M, MS-M and SilverHawk LX-M. These devices are among the latest in plaque excision technology and are designed to treat lesions in arteries above the knee for patients suffering from peripheral artery disease. The SilverHawk LS-M, MS-M and LX-M include MEC (Micro Efficient Compression) Technology, a novel advancement which features precision laser-drilled vent holes in the tip of the catheter. These micro vent holes release fluid pressure, providing more space for the collection of tissue in the tip of the device. This technology has the potential to reduce overall procedure time by enabling physicians to increase tissue collection during plaque removal procedures in large vessels above the knee. In vitro bench test results performed by us have demonstrated up to a 30% increase in tissue capture per insertion compared to the previous device.

In February 2008, we announced the U.S. launch of the SilverHawk-R LS-C or "RockHawk" Peripheral Plaque Excision System for surgical use, designed for the treatment of de novo and restenotic atherosclerotic calcified and non-calcified lesions located in the native peripheral arteries.

Future Products. Future atherectomy products in development include the RockHawk for endovascular use and Gen II SilverHawk. The RockHawk is designed to treat calcified lesions with a stronger blade. The Gen II SilverHawk is designed to improve the procedure time, cutting efficiency and ease of use of the existing SilverHawk system.

## **Thrombectomy Products**

Thrombectomy devices are designed to remove blood clots, or thrombus, in order to re-establish blood flow or to prevent a clot from breaking up and blocking smaller downstream vessels. We offer thrombectomy tools for peripheral vascular and cardiovascular procedures that meet a broad spectrum of physician needs, including the mechanical removal of thrombus and the delivery of peripheral blood clot therapies designed to help dissolve the clot.

Rinspirator Thrombus Removal System. As a result of our acquisition of FoxHollow, we offer the Rinspirator Thrombus Removal System, which removes blood clots from occluded arteries in patients suffering from peripheral artery disease or coronary artery disease. The Rinspirator is designed to be used to simultaneously rinse with physician-specified therapeutic fluids and remove thrombi, emboli and debris from the peripheral and coronary vasculature. Removing the thrombi, emboli and debris prevents such matter from potentially moving downstream and putting patients at risk for distal embolization or future occlusions.

The Rinspirator consists of a hand-held device, tubing connecting the handle to the IV spike and waste bag, as well as a dual-lumen catheter. As the operator squeezes the device, the infusion syringe pushes physician-specified fluids into the catheter and out through the infusion holes at the tip of the catheter, rinsing the vessel. At the same time, the aspiration syringe fills with the aspirated fluids. By gently washing away the debris from the vessel walls, the physician can ensure optimal clearing of the vessel, visualization of the lesion site and reduce the risk for future occlusions.

There are currently four FDA-approved Rinspirator catheter sizes available. All four catheters are approved for use in the peripheral arteries and two are specifically approved for use in both peripheral and coronary arteries.

X-Sizer Thrombectomy Catheter System. The X-Sizer Thrombectomy Catheter System is a self-contained thrombus removal system that uses a helical rotating cutter contained within the tip of an aspiration catheter to shear, capture and remove thrombus. A battery powers the rotating cutter, and aspiration is provided by a disposable vacuum system. We believe that the X-Sizer System offers superior functional characteristics due to its self-contained disposable design, eliminating the need for capital equipment or a temporary pacing catheter. In the United States, the X-Sizer is cleared for use in the mechanical removal of thrombus in synthetic hemodialysis grafts, which are used to facilitate access to the bloodstream in order to enable treatment to filter toxins from the bloodstream in patients with kidney failure. Outside of the United States, the X-Sizer System is approved for use in patients with thrombus in native coronary arteries and saphenous vein bypass grafts.

Helix Clot Buster Thrombectomy Device. The Helix Clot Buster Thrombectomy Device is a mechanical thrombectomy device that macerates thrombus into microscopic particles with little or no interaction with the vessel or graft wall. Maceration of the thrombus is achieved through the use of an enclosed, rapidly rotating compressed-air blade that creates a flow of fluid through side holes in the catheter. Activation is achieved by stepping on a foot pedal, which is connected to a compressed air or nitrogen supply. The Helix system is approved for use in the mechanical dissolution of acute and subacute thrombus within synthetic dialysis grafts and native vessel dialysis fistulae.

Diver C.E. Clot Extraction Aspiration Catheter. We distribute the Diver C.E. Clot Extraction Aspiration Catheter in the United States pursuant to our distribution agreement with Invatec Technology Center GmbH. The Diver is approved for the removal of fresh, soft emboli and thrombi from vessels in the arterial system. We believe the Diver has the benefit of an intuitive, single operator design, it is fully disposable and easy to set up and there is no need for capital equipment.

## Procedural Support Products

As part of our peripheral vascular market strategy, we market and sell a number of products to be used in conjunction with our other peripheral vascular portfolio products, including snares, microsnares, guidewires, catheters and other accessories.

Goose Neck Snares and Microsnares. Foreign objects can be retrieved from the vascular system by using snares and other devices. Examples of foreign objects that require retrieval include broken catheter or guidewire tips, as well as stents that are dislodged from their delivery system and carried downstream. Our Goose Neck Snares and Microsnares incorporate a single, radiopaque (visible under fluoroscopy) loop mounted at the tip of a guidewire. The loop is deployed and retrieved through a catheter. We believe that our snares are

unique because the loop remains positioned at a 90 degree angle relative to the wire. This increases the ability of the loop to encircle the foreign object, thereby improving the rate of success of retrieval. Nitinol shaft technology used in the wire provides kink resistance and durability. Our Goose Neck snares and microsnares are available in a wide variety of sizes for optimal fit within the vessel. Our Goose Neck snares are approved for use in the cardiovascular system or hollow viscus to retrieve and manipulate foreign objects and our Goose Neck microsnares are approved for use in the retrieval and manipulation of atraumatic foreign bodies located in the coronary and peripheral cardiovascular system, and the extra-cranial neurovascular anatomy.

Nitrex Guidewires. Guidewires are threaded through vessels as a first step in most endovascular procedures. Balloon and stent catheters are advanced over guidewires to the target treatment area. For this reason, they are an indispensable component in the catheterization laboratory. Our Nitrex guidewires are characterized by both flexibility and kink resistance which are particularly useful when negotiating tortuous vascular anatomy. Some interventional procedures demand a wire with maximum lubricity, while others require enhanced "purchase" or ability to maintain placement in a vessel. Our Nitrex guidewires offer the ability to maintain placement in the vessel and maximum control through the procedure. Our proprietary manufacturing processes create a wire with a gently tapered, continuous solid nitinol core that extends from the proximal end through the distal tip. Gold tungsten coils provide excellent radiopacity for enhanced visualization and to ensure precise navigation through the vasculature. Our Nitrex guidewires are versatile since they are available in a variety of tip lengths and angles for broad applications and are used in a wide range of endovascular procedures.

Balloon Angioplasty Catheters. We offer a broad portfolio of peripheral vascular balloon angioplasty catheters, which we purchase from Invatec pursuant to our distribution agreement. These include the Admiral Xtreme, Sailor Plus, Submarine Plus and Amphirion Deep, which come in a number of lengths and sizes and are used in a variety of procedures. In the United States, these balloon catheters are cleared for non-coronary dilatation of the vascular anatomy excluding the carotid arteries.

### Our Neurovascular Markets

According to the American Stroke Association, there are approximately 780,000 strokes annually in the United States, making stroke the third leading cause of death and a leading cause of long-term disability. Strokes consist of either blockages (ischemic stroke) or ruptures (hemorrhagic stroke) of vessels within or leading to the brain. Acute ischemic stroke affects approximately 680,000 patients annually while hemorrhagic stroke is a less common disorder, affecting approximately 100,000 patients per year in the United States. Current interventional therapies serve primarily the hemorrhagic stroke market while technologies in development are focused on the larger and underserved ischemic stroke market. The two most common causes of hemorrhagic stroke are ruptures of cerebral aneurysms and arterio-venous malformations, or AVMs.

An aneurysm is a weakening of the vessel wall that forms a balloon-shaped pouch, which fills with blood. Aneurysms typically grow over time and, due to pressure placed on the wall of the aneurysm, are prone to rupture. Ruptured aneurysms can easily result in death as a result of massive intracranial bleeding and loss of perfusion to the brain in the area affected by the aneurysm rupture. While an estimated 21,000 hemorrhagic stroke deaths in the United States in 2007 were caused by ruptured cerebral aneurysms, autopsy studies have suggested that unruptured aneurysms may exist in approximately 2% to 5% of the general population in the United States. We believe that with the development of new diagnostic and interventional technologies, the pool of patients that may benefit from intervention will continue to expand to include increasing numbers of those with unruptured aneurysms discovered in conjunction with other examinations.

Driven by rapid advances in device technology and results from the International Subarachnoid Aneurysm Trial, or ISAT, the results of which were published in *The Lancet* in October 2002, the treatment of both aneurysms and AVMs has been shifting from open surgical techniques to minimally invasive, endovascular techniques. While this market transition has been more rapid in geographies outside of the United States, we estimate that approximately 25% to 40% of aneurysm interventions in the United States now are performed using endovascular techniques.

In an AVM, the flow of blood between arteries and veins, which normally occurs through very small capillary vessels, is short circuited by the development of a network of larger vessels directly connecting the arteries and veins. The higher blood pressure flowing directly to the veins makes these vessels highly prone to rupture. We estimate that approximately 15,000 AVM cases were diagnosed worldwide in 2007.

The primary endovascular procedure for treating both aneurysms and AVMs uses a repair technique called embolization, the objective of which is to induce a blood clot, or thrombus, in the diseased vasculature. The purpose of the thrombus is to limit blood flow through the diseased vascular anatomy, thereby reducing blood pressure and flow to a ruptured area or the likelihood of rupture in an unruptured area. The endovascular embolization of cerebral aneurysms usually involves the deployment of small coils composed of metal or a combination of metal and polymer. The endovascular embolization of AVMs usually involves the deployment of a liquid polymer or very small polymer particles and frequently, subsequent surgical resection of the AVM.

Ischemic stroke occurs when an artery to the brain is blocked. If left untreated for more than a few minutes, brain cells may die due to the lack of blood flow. Ischemic strokes can be caused by several different kinds of disease, with the most common being a narrowing of the arteries caused by atherosclerosis or gradual cholesterol deposits. If arteries become too narrow, clots may form. There are two different types of ischemic stroke: thrombotic and embolic. A thrombotic stroke occurs when arteries in the brain become blocked by the formation of a clot within the brain. Embolic strokes are the result of a clot forming in another part of the body, such as the heart or carotid artery and then traveling to the brain where it lodges and blocks blood flow.

#### Our Neurovascular Product Portfolio

Our neurovascular product portfolio includes embolic coils, liquid embolics, micro catheters, flow directed catheters, occlusion balloon systems, guidewires and neuro stents.

#### Embolic Coils

We believe that embolic coils represent one of the largest categories of products in the neurovascular device market and were used in over 60,000 procedures worldwide in 2007. Embolic coils are used in virtually all endovascular treatments of aneurysms and in some AVMs. Our embolic coil products are delivered using a combination of our minimally invasive guidewires, microcatheters, stents and balloons. During an aneurysm procedure, the embolization coils are attached to a hypotube and are passed through a delivery catheter into the aneurysm space. The coil is then detached from the hypotube, the hypotube is removed and the next coil is advanced through the catheter. This process is repeated until approximately 35% to 45% of the volume of the aneurysm is filled with coils. The procedure requires a high level of precision and skill to avoid either under or over-filling the aneurysm, since over-filling may cause rupture or painful pressure on adjacent tissue and under-filling may permit the aneurysm to reform or grow.

Axium Detachable Coil System. We launched our Axium Detachable Coil System on a worldwide basis in the fourth quarter 2007. Our Axium coils are intended for the endovascular embolization of intracranial aneurysms and the embolization of other neurovascular abnormalities, such as AVMs and arteriovenous fistulae. They are also indicated for use in the European Union for the treatment of peripheral vascular abnormalities. We designed our Axium coils in an effort to meet the performance criteria of a diverse group of leading neurosurgeons and interventional neuroradiologists. Unique features and benefits of our Axium coils include:

- a high degree of coil conformability, which facilitates the physician's goal of more easily and completely filling and packing the aneurysm, regardless of its shape and size;
- coil softness combined with stretch resistance, which allows the coil to be positioned or re-positioned within the aneurysm without adding to the risk of bleeding or hemorrhagic stroke;
- ease of coil placement through the microcatheter, providing the physician with enhanced control and deliverability; and

• rapid, safe and simple detachment of the coil through a proprietary, micro-machined instant detachment system that offers instantaneous coil detachment without the use of wires or syringes, which facilitates precise and rapid coil deployment while minimizing procedure time, which may be especially important in a ruptured aneurysm or when blood flow to the brain has been restricted.

Nexus Embolic Coils. We also offer our Nexus line of coils in the United States and Europe, including our latest addition to the Nexus family, the Nexus Morpheus. Our Nexus coils are intended for the endovascular embolization of intracranial aneurysms that because of their morphology, their location or the patient's general medical condition are considered by the treating neurosurgical team to be very high risk for management by traditional operative techniques or inoperable. Our Nexus coils are also intended for the embolization of other neurovascular abnormalities, such as AVMs and arteriovenous fistulae. Our Nexus line of coils consists of framing, filling and finishing coil offerings, allowing physicians to treat a wide range of aneurysm shapes and sizes. All Nexus coils incorporate a Nitinol filament, which offers improved shape retention and increased resistance to coil compaction. Nexus also incorporates a bioactive microfilament technology to enhance aneurysm healing. The Morpheus is a three-dimensional soft and conformable coil that does not sacrifice the compaction resistance inherent with the Nitinol core.

*NXT*. We also offer our older generation NXT line of detachable coils in the United States and Europe. The NXT family includes framing, filling and finishing coils and are sold in a wide range of shapes and configurations. Many of the NXT products incorporate the use of Nitinol technology, resulting in less stretching for more confident positioning and better resistance to compaction, while its enhanced shape memory provides a more supportive basket and optimal bridging of the neck of the aneurysm.

## Liquid Embolics

We estimate that liquid embolics were used in approximately 14,000 worldwide neurovascular procedures in 2007, including the majority of AVM and some aneurysm procedures. One embolization technique for AVMs involves the injection of acrylic-based glue. We believe, however, that glues have multiple drawbacks including the lack of controlled delivery and extreme adhesion to all surfaces, including that of the delivery catheter. Glue solidifies upon contact with blood which reduces physician control during filling and necessitates very rapid withdrawal of the delivery catheter in order to avoid it being permanently glued in place. We believe our Onyx Liquid Embolic System is a superior solution.

Onyx Liquid Embolic System. Onyx is our proprietary biocompatible copolymer which is delivered, in liquid form, through proprietary microcatheters to blood vessels in the brain, where it fills a vascular defect and transforms into a solid polymer cast. Onyx offers a unique form, fill and seal approach to the interventional treatment of aneurysms and AVMs associated with hemorrhagic stroke. Because Onyx is non-adhesive, and solidifies over a few minutes' time, the injection and filling of the vascular defect can take place in a very controlled manner. When the vascular defect is completely filled with the Onyx polymer cast, the delivery catheter is removed. We believe our randomized clinical trial revealed that Onyx was at least as effective as acrylic-based glue in filling aneurysms, had a better percentage reduction in AVMs and resulted in the use of fewer coils. In addition to providing a controlled and measured delivery, other benefits of Onyx include the soft malleable cast for ease of surgical resection and enhanced radiopacity for bright visualization of material.

In April 2007, we received Humanitarian Device Exemption, or HDE, approval from the FDA for our Onyx HD 500 Liquid Embolic System for the treatment of intracranial aneurysms. This approval allows us to commercialize our Onyx Liquid Embolic System to a population of patients with wide-necked cerebral aneurysms. The approval is limited to saccular, sidewall aneurysms with a dome to neck ratio less than 2 millimeters that are not amenable to treatment with surgical clipping.

#### Micro Catheters

We market several micro catheters that are intended to allow access to, and treatment in, difficult-to-reach anatomical locations such as the remote vessels in the brain or other challenging vascular structures. In

addition to their use with our embolic coils and liquid embolics, these products are compatible with, and are often used with, our competitors' products.

Echelon and Pre-shaped Echelon Micro Catheters. Using a unique blend of materials and construction, our Echelon family of over-the-wire micro catheters provide what we believe to be one of the largest inner channels in its class while still enabling the physician to access difficult anatomy and deliver a wide range of coils. The pre-shaped Echelon catheter represents a key line extension for our Echelon family of products, and offers improved navigation, deliverability and stability.

UltraFlow and Marathon Flow Directed Micro Catheters. The UltraFlow Flow Directed Micro Catheter and Marathon Flow Directed Micro Catheter are intended to access the peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents, such as embolization materials and of diagnostic materials, such as contrast media. The UltraFlow micro catheter is specifically designed to enable access to distal locations and to allow super-selective vessel positioning. The Marathon is an improved flow directed micro catheter that contains both a Nitinol braid and a stainless steel helical wire, which improves navigability while retaining pushability and tip softness. We believe that both the UltraFlow and Marathon micro catheters provide excellent trackability over a wire.

Other Micro Catheters. We also market several other micro catheters, including the Rebar Reinforced Micro Catheter which is designed to deliver a wide variety of pharmacologic, diagnostic and therapeutic agents, including detachable coils and the Onyx Liquid Embolic System, and the Nautica Micro Catheter, which is an over-the-wire micro catheter designed to deliver detachable coils.

## Occlusion Balloon Systems

HyperForm and HyperGlide Occlusion Balloon Systems. Our HyperForm and HyperGlide Occlusion Balloon families are highly flexible balloons designed for use in blood vessels where temporary occlusion is desired. They are useful in selectively stopping or controlling blood flow, and are capable of accessing small diameter vessels and vessels that have many twists and turns. Accordingly, they may be used to control blood flow to remote sites to allow for embolization treatment of vascular abnormalities such as aneurysms.

### Guidewires

Hydrophilic Guidewires. Our portfolio of neurovascular guidewires includes the Mirage Hydrophilic Guidewire. This guidewire is designed for precise torque control and is compatible with several sizes of flow-directed and over-the-wire micro catheters. It assists the physician in micro catheter navigation and remote vessel access while providing a flexible and shapeable tip. Its durable coating allows it to glide through tortuous vasculature. Other hydrophilic guidewires include the SilverSpeed, X-Pedion and the X-Celeràtor.

## Neuro Stents

Stenting is of increasing importance in the aneurysm and ischemic stroke markets. In December 2007, we received a CE mark for the neurovascular use of our new stent platform, the Solitaire. We have initiated limited commercialization of the Solitaire platform, a self-expanding Nitinol stent, for use in bridging the neck of aneurysms to facilitate more secure coil placement, with thrombo-embolic disease to immediately restore blood flow and assist in the removal of clot burden and with intracranial stenotic disease where vessels within the brain become narrowed. The Solitaire products are fully retrievable and detachable, allowing for more precise placement and if required, replacement of the stent is possible.

#### Sales, Marketing and Distribution

#### Structure and Strategy

We have dedicated substantial resources to establish a direct sales capability in the United States, Canada, Europe and other countries as well as establishing distribution networks in selected international markets. We believe our global presence enables us to embrace and capitalize on the growing market for endovascular devices that exists outside of the United States. In addition, our global strategy allows us to commercialize

technologies internationally while pursuing regulatory approval in the United States, increasing near-term sales and helping us refine our commercialization strategies in anticipation of product launches in the United States. As of December 31, 2007, our sales and marketing infrastructure included approximately 400 professionals which consisted of approximately 350 sales professionals in the United States, Canada, Europe and other countries. Individuals in our sales organization generally have substantial medical device experience and are responsible for marketing our products directly to a variety of specialists engaged in endovascular therapies. These direct sales representatives provided 86% and 87% of our net sales in fiscal 2007 and fiscal 2006, respectively, with the balance generated by independent distributors who represent us in certain international markets.

As of December 31, 2007, our global endovascular marketing team was comprised of approximately 50 individuals covering product management, corporate communications and education and training. We devote significant resources to training and educating physicians in the use and benefits of our products. In the United States, we instruct our employees, including our sales professionals, not to discuss the use of our products outside of the FDA-approved indication. If unsolicited questions are posed by physicians, we inform them of the approved use of our products. Although we do not market our products for off-label uses, physicians may choose to use our products as they see fit, including outside of the FDA-approved applications. For example, although our stent products are approved in the United States for use in the biliary duct, as are most competing peripheral stent systems in the United States, some physicians choose to use the stents in peripheral vessels. If the FDA concludes that we promote our device for such off-label uses or that our promotional activities otherwise fail to comply with the FDA's regulations or guidelines, we may be subject to warning letters from, or other enforcement action by, the FDA.

#### United States

As of December 31, 2007, we had approximately 235 sales professionals selling our products in the United States, including 186 direct sales representatives and 24 peripheral vascular consultants selling our peripheral vascular and cardiovascular products and 25 direct sales representatives selling our neurovascular products. Our sales force is organized by geographic sales territories, and each territory is managed by a district sales manager, or direct sales representative, who acts as the primary customer contact. Our regional sales managers supervise the district sales managers and also focus on maintaining key customer relationships.

Since the completion of our acquisition of FoxHollow, we have spent considerable time integrating the two U.S. peripheral vascular sales forces into one combined U.S. peripheral vascular sales force and training sales personnel on our peripheral vascular product portfolio. We reduced the number of sales representatives from approximately 328 at the time of our acquisition of FoxHollow to approximately 210 as of December 31, 2007.

We expanded the sales force selling our neurovascular products in late 2007 from approximately 20 sales representatives to 25 sales representatives as of December 31, 2007 primarily to support the launch of our Axium Detachable Coil System.

In August 2007, we were awarded three, three-year contracts by Novation, the health care contracting and services company of VHA Inc. and the University HealthSystem Consortium, two national health care alliances, covering our peripheral interventional, thrombus management and neuro interventional products. In March 2007, we were awarded a single-source, new technology agreement by Novation for our Onyx Liquid Embolic System.

## Europe and Canada

Our direct selling organization in Europe has a presence in Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, the Netherlands, Norway, Spain, Sweden, Switzerland and the United Kingdom. As of December 31, 2007, our European sales team had 83 sales professionals, managers and support staff, including 35 selling our peripheral vascular and cardiovascular products, 19 selling our neurovascular products and 29 selling both.

We also sell our products in Canada through a five person direct sales force as of December 31, 2007.

#### Other International

In the major markets of Asia Pacific, Latin America, Eastern Europe and the Middle East, we self our products through distributors. In addition to sales, these distributors are involved in product launch planning, education and training, physician support and clinical trial management. Through dedicated distributors and 26 sales professionals as of December 31, 2007, we have a sales presence in all major international markets, including Australia, Brazil, Argentina, Japan and China.

#### Other Distribution Arrangements

In September 2007, we entered into a distribution agreement with Bacchus Vascular, Inc., a provider of medical devices used by interventional radiologists and vascular surgeons for the minimally invasive treatment of deep vein thrombosis and other peripheral vascular disease. The six-year agreement allows Bacchus to sell certain sizes of our EverFlex Self-Expanding Stent System to active customers of Bacchus who are located in the United States and Canada.

In April 2007, we entered into a joint marketing and distribution agreement with Volcano Corporation, under which Volcano has the opportunity to sell our SpiderFX Embolic Protection Device in conjunction with Volcano's Intravascular Ultrasound and Functional Measurement devices for use in saphenous vein grafts in the United States. Volcano's Intravascular Ultrasound and Functional Measurement systems provide real time data that enable endovascular specialists to select, guide and evaluate the appropriate treatment of vascular diseases.

In February 2007, we executed a new distribution agreement with Invatec Technology Center GmbH, which replaced a distribution agreement with Invatec S.r.l. originally dated June 24, 2004. Under the distribution agreement, we have been appointed by Invatec as a non-exclusive distributor of certain of Invatec's products in the United States and Puerto Rico. This arrangement continues to provide us with a broad portfolio of commercially competitive products that complement our existing portfolio. Invatec manufactures and markets a broad line of endovascular products for the peripheral vascular and cardiovascular markets. The Invatec products we distribute include the Sailor Plus, Submarine Plus, Admiral Xtreme and Amphirion Deep PTA catheters and the Diver C.E. Thrombus Aspiration Catheter. The term of the distribution agreement extends until December 31, 2008. Under the distribution agreement, we are permitted to continue to self our inventory of Invatec products for a period of up to six months after the termination of the distribution agreement.

#### Manufacturing

We currently have a manufacturing facility located in Plymouth, Minnesota, at which we manufacture most of our peripheral vascular products, a manufacturing facility located in Irvine, California, at which we manufacture most of our neurovascular products, and a manufacturing facility located in Redwood City, California, at which we manufacture our SilverHawk and Rinspirator products. We manufacture our products at facilities in a controlled environment and have implemented quality control systems as part of our manufacturing processes. We believe we are in material compliance with FDA Quality System Regulations for medical devices, with ISO 9001 quality standards and applicable medical device directives promulgated by the European Union and Canada and ISO/EN 13485, which facilitates entry of our products into the European Union and Canada. The FDA and European Union competent authorities have recently inspected our manufacturing facilities and found no significant issues. We rely on independent manufacturers for certain product components and processes. On an ongoing basis, to improve yields and cycle times, we are investing in developing internal capabilities and applying lean manufacturing concepts at all of our manufacturing facilities.

#### Research and Development

Our research efforts are directed toward the development of new endovascular products that expand the therapeutic alternatives available to physicians, improvements to and extensions of our existing product offerings. Our product development process incorporates teams organized around each of our core technologies, with each team having representatives from research and development, marketing, regulatory, quality, clinical affairs and manufacturing. Consultants are used when additional specialized expertise is required.

Our research and development team has a demonstrated record of new product initiatives and significant product improvements. Specific product improvement initiatives have included:

- broadening acquired technologies in order to address a larger share of the target markets;
- · incorporating important features which we believe appeal to the physicians who use our products; and
- leveraging core technologies to develop new product platforms and enter new markets.

Our research and development expenditures were \$48.4 million in 2007, compared with \$26.7 million and \$39.3 million in 2006 and 2005, respectively. The lower spending levels in 2006 compared to 2005 were primarily due to the completion of certain clinical trials in 2005. Our research and development costs include traditional research and development expenses as well as the cost of our clinical studies.

#### **Clinical Studies**

We support many of our new product initiatives with clinical studies in order to obtain regulatory approval and new indications and provide demonstrated medical evidence and best practices on our technologies. We intend to increase our expenditures on clinical trials in 2008 compared to 2007 as part of the natural migration of our products from development to the clinical validation phase. In 2007, our clinical studies included a focus on product applications for the carotid artery and the SFA. In 2008, our clinical studies are designed to provide both regulatory clearance and clinical indication, as well as provide novel clinical data which will be beneficial for improved peripheral and neurovascular patient treatment worldwide.

The goal of a clinical trial is to meet the primary endpoint, which measures the clinical effectiveness and/or safety of a device and is the basis for FDA or other regulatory approvals. Primary endpoints for clinical trials are selected based on the intended benefit of the medical device. Although clinical trial endpoints are measurements at an individual patient level, the results are extrapolated to an entire population of patients based on clinical similarities to patients in the clinical trials.

We continually evaluate the potential financial benefits and costs of our clinical trials and the products being evaluated in them. If we determine that the costs associated with attaining regulatory approval of a product or new indication exceed the potential financial benefits of that product or new indication, or if the projected development timeline is inconsistent with our investment horizon, we may choose to stop a clinical trial and/or the development of a product.

The following tables summarize our key current and planned clinical trials.

# **Carotid Clinical Trials:**

Trial	Product	Study Design	Status
CREATE Carotid Pivotal Trial (U.S.)	Protégé GPS Stent with an ev3 Embolic Protection Device	Prospective, multi-center single-arm non-inferiority study	Enrollment and follow-up completed
		Primary endpoint of major adverse cardiovascular and cerebral event rate	Met primary endpoint
CREATE Carotid Pivotal- SpideRX Arm (U.S.)	SpideRX Embolic Protection Device, with commercially available Guidant RX ACCULINK Stent	Prospective, multi-center single-arm study, added to CREATE Pivotal study, to confirm safety and effectiveness	Enrollment and follow-up completed
		Primary endpoint of 30-day major adverse cardiovascular cerebral event	Met primary endpoint
CREATE PAS (U.S)	Protégé GPS Stent with an ev3 Embolic Protection Device	Prospective, multi-center single-arm confirmatory post-approval study	Enrollment initiated in second quarter 2007
		Primary endpoint of major adverse cardiovascular and cerebral event rate in broad use at investigative centers	
Embolic Protection Clin	ical Trials:		
Trial	Product	Study Design	Status
SIMPLE Cardio (Europe)	Spider Embolic Protection Device	Prospective, multi-center, single-arm trial to evaluate safety and performance of device when used in patients undergoing saphenous vein graft procedures with percutaneous transcatheter angioplasty catheters	Enrollment and follow-up completed  Results established a 30-day major adverse cardiovascula event rate of 4%
	•	Primary endpoint of major adverse cardiovascular event within 30 days post- procedure	
SPIDER SVG Trial Cardio (U.S. and Canada)	SPIDER and SpideRX Embolic Protection Device	Prospective, multi-center, randomized, non-inferiority trial comparing SPIDER	Enrollment and follow-up completed
		and SpideRX to commercially available embolic protection devices during percutaneous saphenous vein graft procedures	Met primary endpoint
		Primary endpoint of major adverse cardiovascular event within 30 days post- procedure	

Trial	Product	Study Design	Status
RockHawk SpiderFX Trial (U.S.)	SilverHawk Peripheral Calcium Tip Plaque Excision System with SpiderFX Embolic Protection Device	Prospective, multi-center, non-randomized, single-arm study to evaluate the safety and effectiveness of the SilverHawk with Calcium Tip (i.e. RockHawk) Plaque Excision System when used in conjunction with the SpiderFX Embolic Protection Device in the treatment of moderate to heavily calcified lesions in the femoropoplitical arteries	Enrollment anticipated to begin second quarter 2008
Peripheral Stent Clinica	l Trials:		
Trial	Product	Study Design	Status
PROVE-IT (U.S.)	EverFlex stent, Protégé GPS stent, and Visi-Pro stent	Prospective, multi-center, non-randomized, 2-arm study to evaluate the safety and effectiveness of primary stenting compared to PTA performance goals for the treatment of iliac lesions	Enrollment anticipated to begin fourth quarter 2008
		Primary safety endpoint of 30-day major adverse event (self-expanding stent arm)	
	·	Primary effectiveness endpoint of 9-month patency by duplex (self- expanding stent arm)	
		Primary composite endpoint of acute procedure success and 30-day major adverse event (balloon expandable stent arm)	
DURABILITY I (Europe)	EverFlex Stent	Prospective, multi-center, non-randomized study to evaluate the long-term (12-month) patency of the EverFlex stent in SFA lesions	Enrollment complete; follow-up continuing
DURABILITY II (U.S.)	EverFlex Stent	Prospective, multi-center, non-randomized study to evaluate the safety and effectiveness of the primary stenting compared to PTA performance goals for the treatment of SFA lesions Primary safety endpoint of 30-day major adverse event Primary effectiveness endpoint of 12-month	Enrollment and follow-up continuing
	·	patency by duplex	•

Trial	Product	Study Design	Status	
PROSPERO (Europe)	EverFlex Stent	Prospective, multi-center, observational patient registry to evaluate the long term (12-month) integrity and effectiveness of the Protégé EverFlex stent in the SFA in the real world practice	Enrollment complete; follow-up continuing	
SilverHawk Clinical Tri	als: Product	Study Design	Status	
RockHawk SpiderFX Trial (U.S.)	SilverHawk Peripheral Calcium Tip Plaque Excision System with SpiderFX Embolic Protection Device	Prospective, multi-center, non-randomized, single-arm study to evaluate the safety and effectiveness of the SilverHawk with Calcium Tip (i.e. RockHawk) Plaque Excision System when used in conjunction with the SpiderFX Embolic Protection Device in the treatment of moderate to heavily calcified lesions in the femoropopliteal arteries	Enrollment anticipated to begin in second to third quarter 2008	
SilverHawk PAS (US)	SilverHawk	Prospective, multi-center, non-randomized, single-arm study to evaluate the long term safety and efficacy of the SilverHawk Atherectomy Catheter as compared to PTA performance goals during endovascular treatment of peripheral artery disease in the femoropopliteal arteries	Enrollment anticipated to begin in third quarter 2008	
Neuro Clinical Trials:				
Trial	Product	Study Design	Status	
Solitaire Stent Flow Restoration Trial	Solitaire Stent	In development	Enrollment anticipated to begin fourth quarter 2008	
Restoration That		US IDE, prospective, single-arm, multi-center study		
		FDA approval		
Axium Post Market and Expanded Approvals Trial	Axium Coil	In development	Enrollment anticipated to begin second quarter 2008	
		Prospective, single-arm, multi-center study	oegiii seediid quarei 2008	
		Scientific clinical data and possible regulatory submissions		
Onyx HD	Onyx HD Liquid Embolic	Onyx HD-500 was approved through the FDA HDE process, and thus requires that each U.S. physician obtain Institutional Review Board ("IRB") approval prior to use		

## Collaboration with Merck & Co., Inc.

As a result of our acquisition of FoxHollow, we assumed FoxHollow's obligations under a collaboration and license agreement with Merck & Co., Inc., pursuant to which the parties agreed to collaborate on the analysis of atherosclerotic plaque removed from patient arteries with the goal of identifying new biomarkers of atherosclerotic disease progression. Under the agreement, Merck agreed to pay FoxHollow \$40.0 million in equal installments over the initial four-year term of the research collaboration, in exchange for FoxHollow's agreement to collaborate exclusively with Merck during such period with respect to certain fields, which generally involve the use of extracted plaque and other human tissue for the identification or development of drugs, drug targets, and biomarkers, certain drug delivery applications and the development of non-invasive external imaging technologies. Merck may extend these exclusivity obligations, on a year-to-year basis, in the event it also elects to extend the term of the collaboration beyond the initial four-year term, by making additional payments to us of \$10.0 million per year, which Merck may offset against its royalty and milestone obligations during such year.

Under the agreement, Merck also agreed to provide a minimum of \$60.0 million in funding to FoxHollow over the first three years of the four-year collaboration program term, for research activities to be conducted by FoxHollow under Merck's direction. In the event Merck extends the collaboration beyond its initial four-year term, Merck would be required to fund our additional activities under the collaboration on an asperformed basis. We will receive milestone payments on successful development of drug products or diagnostic tests utilizing results from the collaboration, as well as royalties on sales by Merck of drugs and diagnostic products developed through the collaboration.

The agreement was amended in connection with our acquisition of FoxHollow and as amended provides that Merck may terminate the collaboration at any time after the initial four-year term upon advance notice to us and that either we or Merck may terminate the collaboration upon certain uncured material breaches of the agreement by the other party or as result of a bankruptcy filing by or against the other party. Merck also has the right to terminate the collaboration in the event that John B. Simpson, M.D., Ph.D., FoxHollow's founder and former chief executive officer, is no longer a director of our company other than in the event of his death or disability. As a result of Dr. Simpson's resignation from our board of directors in February 2008, Merck has the right to terminate the collaboration and license agreement. Merck may exercise this right at any time within six months of Dr. Simpson's resignation. Although we have been given no indication from Merck, who has a representative on our board of directors, that Merck plans to exercise its termination right under the agreement, no assurance can be provided that Merck will not exercise its right and terminate the agreement. Since the payments we currently receive from Merck are for exclusivity and collaboration, if Merck cancels the agreement completely — including both the exclusivity and collaboration portions of the agreement — we will lose future revenue, but also will not be required to incur certain, significant expenses associated with the collaboration. If Merck cancels the collaboration portion of the agreement, but not the exclusivity portion, we will continue to be entitled to exclusivity payments from Merck through at least 2010, but we will not incur certain, significant expenses associated with the collaboration.

#### **Government Regulation**

## **United States**

Our products are regulated in the United States as medical devices by the FDA and other regulatory bodies. FDA regulations govern, among other things, the following activities that we perform:

- product design, development and manufacture;
- · conduct of clinical trials;
- · product safety, testing, labeling and storage;
- · submission to FDA for pre-marketing clearance or approval;
- record keeping procedures;

- · product marketing, sales and distribution; and
- · post-marketing surveillance, reporting of deaths or serious injuries and medical device reporting.

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or prior pre-market approval from the FDA. The FDA classifies medical devices into one of three classes, depending on the degree of risk associated with each medical device and the extent of controls that are needed to ensure safety and effectiveness. Devices deemed to pose the least risk are placed in class I. Intermediate risk devices are placed in class II, which, in most instances, requires the manufacturer to submit to the FDA a pre-market notification requesting authorization for commercial distribution, known as "510(k) clearance." A 510(k) clearance is provided when the device is deemed "substantially equivalent" to a predicate device, i.e. one that was previously approved by the FDA. Class II 510(k) devices may subject the device to special controls such as performance standards, guidance documents specific to the device or post-market surveillance. Most class I and some low-risk class II devices are exempted from this 510(k) requirement. Class III devices are deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed to be not substantially equivalent to previously cleared 510(k) devices. In general, a class III device cannot be marketed in the United States unless the FDA approves the device after submission of a pre-market approval application.

510(k) Clearance Pathway. When we are required to obtain 510(k) clearance for devices that we wish to market, we must submit a pre-market notification to the FDA demonstrating that the device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 (or to a pre-1976 class III device for which the FDA has not yet called for the submission of pre-market approval applications). In essence, the basic safety and effectiveness of the predicate device supports clearance of the new product. The 510(k) applicant is only required to demonstrate substantial equivalence to the predicate device. The FDA attempts to respond to a 510(k) pre-market notification within 90 days of submission of the notification, but the response may be a request for additional information or data, sometimes including clinical data. As a practical matter, pre-market clearance can take significantly longer than 90 days, including up to one year or more.

After a device receives 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, will require a new 510(k) clearance or could require pre-market approval. In addition, new "claims" not found in the cleared labeling for the device can be deemed a new intended use and can trigger the requirement for a new 510(k). The FDA requires each manufacturer to make its own determination whether a change requires a new 510(k), but the FDA can review and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination that a new clearance or approval is not required for a particular modification, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or pre-market approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Pre-Market Approval Pathway. A pre-market approval, or PMA, application must be submitted if the device cannot be cleared through the 510(k) process. The PMA process is much more demanding than the 510(k) pre-market notification process. A PMA application must be supported by extensive data and information including, but not limited to, technical, pre-clinical, clinical, manufacturing and labeling, to establish to the FDA's satisfaction the safety and effectiveness of the device.

If the FDA determines that a PMA application is complete, the FDA can accept the application and begins an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an accepted PMA application, although the review generally occurs over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the Quality System Regulations. New PMA applications or supplemental PMA applications are required for significant

modifications to the manufacturing process, labeling, use and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as a pre-market approval, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials. A clinical trial is almost always required to support a PMA application. Historically, clinical trials were infrequently required for a 510(k) clearance. Today, information from clinical trials is increasingly required to support FDA clearance. Clinical trials for a "significant risk" device require submission of an application for an investigational device exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials for a significant risk device may begin once the application is approved by the FDA and the Institutional Review Board, or IRB, overseeing the clinical trial. If the product is deemed a "non-significant risk" device under FDA regulations, only the abbreviated IDE requirements apply. Clinical trials must be monitored by the study sponsor and are subject to extensive record keeping and reporting requirements and abbreviated IDE regulations apply. Clinical trials must be conducted under the oversight of an IRB at the relevant clinical trials site and in accordance with applicable regulations and policies including, but not limited to, the FDA's good clinical practice, or GCP, requirements.

For the protection of human subjects in a clinical trial, the FDA and IRB require patients to be informed of both the benefits and risks of the investigational device and the treatment and/or procedure. This is called "informed consent" and the subject must sign a written document stating that he or she understands the risks and consent to be involved in the trial. In addition, study subjects are protected by the Health Insurance Portability and Accountability Act of 1996, or HIPAA. The study subject is asked to provide authorization to the clinical trial site and manufacturer so they can use certain personally identifiable health information about the patient from the clinical trial for use in seeking FDA approval and any other specified uses outlined in the HIPAA authorization.

The study sponsor, the FDA or the IRB at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. The FDA may inspect a clinical investigation and, if it determines that the study sponsor failed to comply with the FDA regulations governing clinical investigations, it may issue a warning letter to or take other enforcement action against the study sponsor, the clinical investigation site or the principal investigator. There is always a risk that the results of clinical testing may not be sufficient to obtain approval of the product.

De Novo Pathway. There is another pathway that may be used to market a medical device. This is called the "de novo" clearance which was established by the Food and Drug Administration Act of 1997, known as "FDAMA." The de novo pathway is for products that do not qualify for 510(k) clearance because there is no predicate upon which to claim substantial equivalence. If the FDA, after reviewing a 510(k) application, sends a "not substantially equivalent" or "NSE" letter to a manufacturer, that manufacturer can request a de novo clearance. This is done by making the request in writing within 30 days of receipt of the NSE letter. The FDA then has 60 days to review the 510(k) application de novo and decide whether to clear the product. If the product is cleared via this pathway, the Agency publishes the clearance in the Federal Register and the cleared product receives a 510(k) and becomes a predicate for future products. If the product fails to be cleared by this pathway, it can only be approved via the PMA pathway.

Humanitarian Device Exemptions. A Humanitarian Device Exemption, or HDE, authorizes the marketing of a humanitarian use device for a limited patient population. An HDE designation is based on the FDA's determination that a device is intended for the treatment and diagnosis of a disease or condition that affects fewer than 4,000 individuals in the United States per year. Once an HDE designation has been obtained, an applicant may seek marketing approval under an HDE. While the HDE application is similar to a pre-market approval application and requires a demonstration of safety, unlike a pre-market approval application, an

HDE does not require a demonstration of effectiveness. Certain limitations apply to the sale and use of devices under an HDE.

Post-Marketing Requirements. After a device is approved for marketing, numerous regulatory requirements apply, including:

- Quality System Regulations, which require manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;
- labeling, advertising and promotion regulations, which govern product labels and labeling, prohibit the
  promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling and
  promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device
  may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely
  cause or contribute to a death or serious injury if it were to recur; and
- · notices of correction or removal, and recall-regulations.

The advertising and promotion of "restricted" devices, i.e. those requiring a prescription, are regulated by the FDA. The advertising and promotion of all other devices are regulated by the Federal Trade Commission, or FTC, and by state regulatory and enforcement authorities. But the FDA often asserts itself in those situations as well because it has continuing authority over the labeling of a product that can be affected by the way it is advertised. Recently, some promotional activities for FDA-regulated products have been the subject of enforcement actions brought under health care reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act, competitors and others can initiate litigation relating to advertising claims.

We have registered with the FDA as a medical device manufacturer. Compliance with regulatory requirements is tested through periodic, pre-scheduled or unannounced "for cause" facility inspections by the FDA and these inspections may include the manufacturing facilities of our subcontractors. "For cause" inspections are generally conducted when FDA suspects the manufacturer is in serious violations of current Good Manufacturing Practice regulations that have not been remedied. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- · warning letters, fines, injunctions, and civil penalties;
- repair, replacement, refund, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing a request for 510(k) clearance or pre-market approval of new products;
- withdrawing 510(k) clearance or pre-market approvals that are already granted; and
- · criminal prosecution.

## International

We conduct sales and marketing activities in various foreign countries. Most major markets have different levels of regulatory requirements for medical devices. Modifications to the approved products require a new regulatory submission in all major markets. The regulatory requirements, and the review times, vary significantly from country to country. Our products can also be marketed in several other countries that have minimal requirements for medical devices. Frequently, we obtain regulatory approval for medical devices in foreign countries first because their regulatory approval is faster and simpler than the FDA. However, as a general matter, foreign regulatory requirements are becoming increasingly stringent.

In the European Union, a single regulatory approval process has been created, under the European Medical Devices Directive, and approval is represented by the "CE Mark." In the EU, the EC uses third parties

called "notified bodies," to review products for approval. They are private, independent third parties certified by the "competent authorities" (or countries) to review and approve medical device applications and grant the CE Mark in the EU. The competent authorities designate and accredit and otherwise oversee the notified bodies they accredit. To obtain a CE Mark in the European Union, defined products must meet minimum standards of safety and quality and then comply with one or more of a selection of conformity routes. The European Community has regulations similar to that of the FDA for the advertising and promotion of medical devices, clinical investigations, and adverse events. Certification of our quality system for product distribution in the European Union is performed by Société Générale de Surveillance, located in the United Kingdom.

! In Japan, medical devices must be approved prior to importation and commercial sale by the Ministry of Health, Labor and Welfare, or MHLW. Manufacturers of medical devices outside of Japan that do not operate through a Japanese entity are required to use a contractually bound in-country caretaker to submit an application for device approval to the MHLW. The MHLW evaluates each device for safety and efficacy. As part of the approval process, the MHLW may require that the product be tested in Japanese laboratories. The approval process ranges in length and certain medical devices may require a longer review period for approval. Once approved, the manufacturer may import the device into Japan for sale by the manufacturer's contractually bound office, importer or distributor. After a device is approved for importation and commercial sale in Japan, the MHLW continues to monitor sales of approved products for compliance with labeling regulations, which prohibit promotion of devices for unapproved uses, and reporting regulations, which require reporting of product malfunctions, including serious injury or death caused by any approved device.

In addition to MHLW oversight, the regulation of medical devices in Japan is also governed by the Japanese Pharmaceutical Affairs Law, or PAL. PAL was substantially revised in July 2002, and the new provisions were implemented in stages through April 2005. The revised law changes class categorizations of medical devices in relation to risk, introduces a third-party certification system, strengthens safety countermeasures for biologically derived products and reinforces safety countermeasures at the time of resale or rental. Review times for our device applications under the new PAL range from one year if clinical data is not required to up to two years if clinical data is required. These review times are expected to be reduced to six months and one year, respectively, as performance standards are released for various product categories.

You should read the information set forth under "Item 1A. Risk Factors — Our products and product development and marketing activities are subject to extensive regulation as a result of which we may not be able to obtain required regulatory approvals for our products in a cost-effective manner or at all, which could adversely affect our business and operating results."

## Fraud and Abuse Laws

A variety of federal and state laws apply to the sale, marketing and promotion of medical devices that are paid for, directly or indirectly, by federal or state health care programs, such as Medicare, Medicaid and TRICARE. The restrictions imposed by these laws are in addition to those imposed by the FDA, FTC and corresponding state agencies. Some of these laws significantly restrict or prohibit certain types of sales, marketing and promotional activities by medical device manufacturers. Violation of these laws can result in significant criminal, civil, and administrative penalties, including imprisonment of individuals, fines and penalties and exclusion or debarment from federal and state health care and other programs.

The principal federal laws include: (1) the Anti-Kickback Statute, which prohibits offers to pay or receive remuneration of any kind for the purpose of inducing or rewarding referrals of items of services reimbursable by a federal healthcare program; (2) the False Claims Act, which prohibits the submission of false or otherwise improper claims for payment to a federally-funded health care program; (3) the Stark law, which prohibits physicians from referring Medicare or Medicaid patients to an entity for the provision of certain designated health services if the physician (or a member of the physician's immediate family) has a financial relationship with that entity, and (4) HIPAA, which prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors, and falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

#### Privacy and Security

HIPAA requires certain "covered entities" to comply with established standards regarding the privacy and security of protected health information, or PHI, and to use standardized code sets when conducting certain electronic transactions. HIPAA further requires that covered entities enter into agreements meeting certain regulatory requirements with their "business associates," which effectively obligate the business associates to safeguard the covered entity's protected health information against improper use and disclosure. While not directly regulated by HIPAA, a business associate may face significant contractual liability pursuant to such an agreement if the business associate breaches the agreement or causes the covered entity to fail to comply with HIPAA. The company often has possession of PHI in situations such as where clinical studies are conducted or sales representatives are asked by a surgeon to be in a surgical suite to provide technical advice on a device during surgery. HIPAA does not require a business associate agreement to be signed in these circumstances. In the course of our business operations, we may become the business associate of one or more covered entities. Accordingly, we may incur compliance related costs in meeting HIPAA-related obligations under business associates agreements to which we become a party.

The European Union has its own privacy standards to which we are subject. Recognizing that our business continues to expand internationally, we intend to review our compliance with these standards and update or enhance our procedures and practices.

#### Third Party Reimbursement

In the United States, as well as in foreign countries, government-funded or private insurance programs, commonly known as third-party payors, pay the cost of a significant portion of a patient's medical expenses. A uniform policy of reimbursement does not exist among all these payors. Therefore, reimbursement can be quite different from payor to payor. We believe that reimbursement is an important factor in the success of any medical device. Consequently, we seek to obtain reimbursement for all of our products.

Reimbursement in the United States depends on our ability to obtain FDA clearances and approvals to market these products. Reimbursement also depends on our ability to demonstrate the short-term and long-term clinical and cost-effectiveness of our products from the results we obtain from clinical experience and formal clinical trials. We present these results at major scientific and medical meetings and publish them in respected, peer-reviewed medical journals.

The United States Center for Medicare and Medicaid Services, or CMS, sets reimbursement policy for the Medicare program in the United States. CMS policies may alter coverage and payment for vascular device technologies in the future. These changes may occur as the result of National Coverage Decisions issued by CMS headquarters or as the result of local or regional coverage decisions by contractors under contract with CMS to review and make coverage and payment decisions. This administration has a national coverage policy, which provides for the diagnosis and treatment of vascular disease in Medicare beneficiaries. We estimate that more than 50% of vascular procedures are performed on patients covered by Medicare. Commercial payor coverage for vascular disease varies widely across the United States.

All third-party reimbursement programs, whether government funded or insured commercially, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling health care costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, second opinions required prior to major surgery, careful review of bills and exploration of more cost-effective methods of delivering health care. These types of programs and legislative changes to reimbursement policies could potentially limit the amount which health care providers may be willing to pay for medical devices.

#### International Trade

The sale and shipment of our products and services across international borders, as well as the purchase of components and products from international sources, subject us to extensive governmental trade regulations. A variety of laws and regulations, both in the United States and in the countries in which we transact business, apply to the sale, shipment and provision of goods, services and technology across international borders, which

include import and export laws and regulations, anti-boycott laws and anti-bribery laws. Because we are subject to extensive regulations in the countries in which we operate, we are subject to the risk that laws and regulations could change in a way that would expose us to additional costs, penalties or liabilities.

#### Environmental

We are subject to various environmental health and safety laws, directives and regulations both in the U.S. and abroad. Our operations, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We do not expect that compliance with environmental protection laws will have a material impact on our capital expenditures, earnings or competitive position. Given the scope and nature of these laws, however, there can be no assurance that environmental laws will not have a material impact on our results of operations. Our leased Redwood City facility sits on property formerly occupied by Rohm & Haas and Occidental Chemical Company and contains residual contamination in soil and groundwater from these past industrial operations. Rohm & Haas and Occidental Chemical Company previously performed soil remediation on the property under the supervision of the California Regional Water Quality Control Board. Rohm & Haas has indemnified the owner of the facility and its tenants against costs associated with the residual contamination.

#### Competition

We compete primarily on the basis of our ability to treat vascular diseases and disorders safely and effectively. Our success can be impacted by the ease and predictability of product use, adequate third-party reimbursement, brand name recognition and cost. We believe we compete favorably with respect to these factors, although there can be no assurance that we will be able to continue to do so in the future or that new products that perform better than those we offer will not be introduced. We believe our continued success depends on our ability to:

- continue to innovate and maintain scientifically advanced technology, being responsive to the changing needs of our diverse customer base;
- · apply our technology across disease states, product lines and markets:
- · attract and retain skilled personnel;
- · obtain and maintain regulatory approvals; and
- · cost-effectively manufacture and successfully market our products.

The markets in which we compete are highly competitive, subject to change and impacted by new product introductions and other activities of industry participants. Several of our competitors have significant financial and human capital resources and have established reputations with our target physician customers. These competitors include Abbott Laboratories, Boston Scientific Corporation, Cook Incorporated, Cordis Corporation (a Johnson & Johnson company) and Medtronic, Inc. We also compete with smaller manufacturers within at least one of the two markets we target. In the peripheral vascular and cardiovascular market, we compete against, among others: C.R. Bard, Inc., Possis Medical, Inc., Cardiovascular Systems, Inc., Pathway Medical Technologies, Inc. and Spectranetics Corporation. In the neurovascular market, we compete with manufacturers of embolic coils and related devices, including Balt Extrusion, Terumo/MicroVention, Inc. and Micrus Corporation. In addition, we compete with a number of drug therapy treatments manufactured by major pharmaceutical companies, including Otsuka Pharmaceutical, the manufacturer of Pletal, and Sanofi Aventis, the manufacturer of Plavix.

Our competitors dedicate significant resources to aggressively promote their products. Competitors may develop technologies and products that are safer, more effective, easier to use or less expensive than ours. To compete effectively, we will need to continue to demonstrate that our products are attractive alternatives to other devices and treatments, differentiating them on the basis of safety, efficacy, performance, ease of use, brand and name recognition, reputation and price. We have encountered and expect to continue to encounter potential physician customers who, due to existing relationships with our competitors, are committed to or

prefer the products offered by these competitors. Several of our physician customers like to experiment with new technologies. Within the atherectomy market, although we believe our SilverHawk product competes favorably against other competing technologies, surgical procedures and pharmaceutical products, recently introduced atherectomy products or products that will likely be introduced to the market shortly may adversely affect future sales of our SilverHawk product, at least in the short term while physician customers experiment with such new products.

### **Employees**

As of December 31, 2007, we had approximately 1,600 employees worldwide. From time to time, we also employ independent contractors to support our operations.

#### **Intellectual Property Rights**

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain protection of the proprietary aspects of our technology. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to aggressively protect our intellectual property that we consider important to our business.

We have developed a patent portfolio internally, as well as through acquisitions, that cover many aspects of our product offerings. As of December 31, 2007, we had 373 issued patents and over 305 pending patent applications in the United States, Europe, Japan, Australia, Canada and other countries throughout the world. The expiration dates of our material patents range from 2009 to 2024. Additionally, we own or have rights to material trademarks or trade names that we use in conjunction with the sale of our products.

We continue to invest in internal research and development of concepts and product ideas for the peripheral vascular and neurovascular markets. This, combined with our patent program, has increased the number of patentable concepts we generate. We also continually evaluate the potential financial benefits and costs of the development of our products and maintenance of our intellectual property rights. If we determine that the costs associated with developing our products and/or maintaining our intellectual property rights exceed the potential financial benefits of that product or right, or if the projected development timeline is inconsistent with our investment horizon, we may choose to stop development of a product and sell the underlying intellectual property rights. For example, in June 2007, we entered into an agreement with Atritech, Inc. pursuant to which we sold and licensed, on a royalty-free perpetual basis, certain intellectual property relating to percutaneously delivered implants within the left atrial appendage for prevention of emboli migration out of the appendage.

We manufacture and market our products both under our own patents and under our license agreements with other parties. Additionally, we are the sales representative and distributor of product lines of Invatec, which has its own proprietary and patented technology.

While we believe that our patents are valuable, our knowledge and experience, our creative product development teams and marketing staff, and our confidential information regarding manufacturing processes, materials and product design have been equally important in maintaining our proprietary product offering. To protect that value, we have instituted policies and procedures, as well as a requirement that, as a condition of employment, all employees execute a confidentiality agreement relating to proprietary information and the assignment of intellectual property rights to us.

We also rely on unpatented proprietary technology. We seek to protect our trade secrets and proprietary know-how, in part, with confidentiality agreements with consultants, vendors and employees.

Despite measures we have taken to protect our intellectual property, we cannot be certain that such measures will be successful or that unauthorized parties will not copy aspects of our products or obtain and use information that we regard as proprietary. In such instances, we may not have adequate remedies for any such breach. These and other risks related to our intellectual property rights are described in more detail under "Item 1A. Risk Factors. If third parties claim that we infringe upon their intellectual property rights, we may incur liabilities and costs and may have to redesign or discontinue selling the affected product," "Item 1A.

Risk Factors — We are currently a party to a number of intellectual property claims, which are costly to defend and the resolution of which could have a material adverse effect on our business and results of operations." and "Item 1A. Risk Factors — If our patents and other intellectual property rights do not adequately protect our products, we may lose market share to our competitors, which would harm our business."

### Forward-Looking Statements

This annual report on Form 10-K contains and incorporates by reference not only historical information, but also forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the safe harbor created by those sections. In addition, we or others on our behalf may make forward-looking statements from time to time in oral presentations, including telephone conferences and/or web casts open to the public, in press releases or reports, on our Internet web site or otherwise. All statements other than statements of historical facts included in this report that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements including, in particular, the statements about our plans, objectives, strategies and prospects regarding, among other things, our financial condition, results of operations and business. We have identified some of these forward-looking statements with words like "believe," "may," "could," "might," "forecast," "possible," "potential," "project," "will," "should," "expect," "intend," "plan," "predict," "anticipate," "estimate," "approximate" or "continue" and other words and terms of similar meaning. These forward-looking statements may be contained in the notes to our consolidated financial statements and elsewhere in this report, including under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Forward-looking statements involve risks and uncertainties. These uncertainties include factors that affect all businesses as well as matters specific to us. Some of the factors known to us that could cause our actual results to differ materially from what we have anticipated in our forward-looking statements are described under the heading "Item 1A. Risk Factors" below.

We wish to caution readers not to place undue reliance on any forward-looking statement that speaks only as of the date made and to recognize that forward-looking statements are predictions of future results, which may not occur as anticipated. Actual results could differ materially from those anticipated in the forwardlooking statements and from historical results, due to the risks and uncertainties described under the heading "Item 1A. Risk Factors" below, as well as others that we may consider immaterial or do not anticipate at this time. Although we believe that the expectations reflected in our forward-looking statements are reasonable, we do not know whether our expectations will prove correct. Our expectations reflected in our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties, including those described below under the heading "Item 1A. Risk Factors." The risks and uncertainties described under the heading "Item 1A. Risk Factors" below are not exclusive and further information concerning us and our business, including factors that potentially could materially affect our financial results or condition, may emerge from time to time. We assume no obligation to update forwardlooking statements to reflect actual results or changes in factors or assumptions affecting such forward-looking statements. We advise you, however, to consult any further disclosures we make on related subjects in our quarterly reports on Form 10-Q and current reports on Form 8-K that we file with or furnish to the Securities and Exchange Commission.

#### **Available Information**

ev3 LLC, our predecessor company prior to our initial public offering in June 2005, was formed in September 2003. Immediately prior to the consummation of our initial public offering in June 2005, ev3 LLC merged with and into us, at which time we became the holding company for all of ev3 LLC's subsidiaries. Our principal executive offices are located at 9600 54th Avenue North, Suite 100, Plymouth, Minnesota 55442. Our telephone number is (763) 398-7000, and our Internet web site address is www.ev3.net. We are a Delaware corporation. The information contained on our web site or connected to our website is not incorporated by reference into and should not be considered part of this report.

We make available, free of charge and through our Internet web site, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. We also make available, free of charge and through our Internet web site under the Investor Relations — Corporate Governance section, to any stockholder who requests, the charters of our board committees and our Code of Business Conduct and Code of Ethics for Senior Executive and Financial Officers. Requests for copies can be directed to Investor Relations at (949) 680-1375.

#### ITEM 1A. RISK FACTORS

The following are significant factors known to us that could materially adversely affect our business, financial condition or operating results.

#### Risks Related to Our Business and Industry

We have a history of net losses and no assurance can be provided that we will achieve profitability.

We are not profitable and had a net loss of approximately \$165.7 million for the fiscal year ended December 31, 2007. Although we expect to be profitable in the foreseeable future, no assurance can be provided that we will achieve profitability in the foreseeable future, or ever. Our short commercialization experience, our recent acquisition of FoxHollow and the integration activities in connection with such acquisition make it difficult to predict our future performance and our failure to accurately predict future performance may lead to volatility in the price of our common stock. Our ability to achieve cash flow positive operations will be influenced by many factors, including the extent and duration of our future operating losses, the level and timing of future sales and expenditures, our ability to integrate FoxHollow's operations with ours and to do so in a timely basis and in so doing, to increase net sales and decrease costs, market acceptance of our products, the results and scope of ongoing research and development projects, competing technologies, market and regulatory developments, the future course of intellectual property and other litigation and the other risks described in this section. If we do not achieve profitability within expected time frames, our business and stock price will be negatively impacted.

We have experienced and may continue to experience difficulties in integrating FoxHollow's operations into ours and may not be unable to realize the anticipated cost savings, net sales and other potential benefits of our acquisition of FoxHollow in a timely manner or at all. As a result, our business, operating results and stock price may be adversely affected.

Our acquisition of FoxHollow, which we completed in October 2007, was a significant transaction for us. The success of this acquisition will depend, in part, on our ability to achieve the anticipated cost savings, net sales and other potential benefits of the acquisition. Our success in realizing these anticipated potential benefits, however, depends in part upon our ability to integrate successfully the two businesses in an efficient and effective manner. The integration of two independent companies is a complex, costly and time-consuming process. Although we have completed the combination of our and FoxHollow's U.S. peripheral vascular sales forces and integrated other sales-related and other functions, these integration activities have not progressed as smoothly as anticipated and to some extent have adversely affected our business, ongoing operations and operating results. Our U.S. peripheral vascular business in particular was negatively impacted by greater than anticipated sales force integration challenges related to our FoxHollow acquisition and higher than expected customer inventory levels of SilverHawk products. Although we believe that certain actions we have taken, including eliminating a layer of sales management and optimizing the size of our U.S. peripheral vascular sales organization, will enable us to overcome the integration challenges and support our future growth objectives, no assurance can be provided that such actions will do so and we still expect such challenges and factors to continue to adversely affect our net sales into the second half of 2008.

The difficulties of combining FoxHollow's operations with ours include, among other factors:

· executing on the strategic vision we communicated to our customers regarding the acquisition;

- · coordinating and consolidating geographically separated organizations, systems and facilities;
- coordinating sales and marketing efforts to effectively communicate our capabilities and effectively cross-sell our products;
- expanding the sale of FoxHollow's products into our international operations and distribution network;
- combining our and FoxHollow's sales force territories and competencies associated with the sale of our products;
- · maintaining key employees and employee morale;
- addressing possible differences in business backgrounds, corporate cultures and management philosophies;
- coordinating research and development activities to accelerate introduction of new products and technologies with reduced costs;
- preserving our customer, distribution, reseller, manufacturing, supplier, marketing and other important relationships and resolving any potential conflicts;
- integrating numerous operating systems, including those involving management information, purchasing, accounting and finance, sales, billing, payroll, employee benefits and regulatory compliance;
- · reconciling inconsistent standards, controls, procedures and policies; and
- creating a consolidated internal control over financial reporting structure to enable us and our independent public registered accounting firm to report on the effectiveness of our internal control over financial reporting.

Although we currently estimate one-time transaction and integration-related cash payments relating to the FoxHollow acquisition to be between approximately \$71 million to \$73 million, this estimate may prove to be inaccurate. In addition, the integration of FoxHollow's operations into ours has already resulted in and may result in additional and unforeseen expenses, loss of key employees, diversion of our management and the disruption or interruption of, or the loss of momentum in, our ongoing business. For example, John B. Simpson, M.D., Ph.D., the founder and former chief executive officer of FoxHollow resigned in February 2008 as a director and employee of our company. It is possible that either internal or external disruption caused by Dr. Simpson's resignation could adversely affect our business and future net sales. Our inability to successfully complete the integration of FoxHollow's operations into ours, to do so within a longer time frame than expected or any failure to achieve the full extent of, or any of, the anticipated operating and cost synergies or long-term strategic benefits of the acquisition could continue to have an adverse effect on our business, operating results and stock price.

Elevated inventory levels of our SilverHawk product at some of our customers adversely affected our operating results for the fourth quarter 2007 and are expected to continue to adversely affect our operating results into the second half of 2008.

We believe that higher than expected customer inventory levels of our SilverHawk product at some of our customers adversely affected our fourth quarter 2007 net sales. While we believe that customer inventory levels in certain customer accounts are beginning to return to more normal levels, we still expect that such elevated inventory levels, as well as continued sales force integration challenges, could adversely affect our net sales into the second half of 2008. No assurance can be provided, however, that such elevated inventory levels will not adversely affect our net sales beyond 2008. In addition, while we have put additional systems in place to better manage field inventory, such as our radio frequency inventory tracking system, commonly known as RFID, that will enable us to more accurately and efficiently track field inventory levels, no assurance can be provided that such systems will improve our field inventory levels or result in better asset management.

As a result of the resignation of John B. Simpson, M.D. Ph.D. as a director of our company, Merck & Co., Inc. has the right to terminate the collaboration and license agreement with us. Any loss of revenue from our relationship with Merck as a result of Merck's termination of the agreement or otherwise could have a significant adverse affect on our operating results and our stock price.

Whether Merck & Co., Inc. will continue to provide revenue to us in the future will depend upon whether Merck exercises its right to terminate the amended and restated collaboration and license agreement dated September 26, 2006 and the level of support and the commitment made by us to fulfill the terms of the agreement. As a result of Dr. Simpson's resignation from our board of directors in February 2008, Merck has the right to terminate the collaboration and license agreement. Merck may exercise this right at any time within six months of Dr. Simpson's resignation. Although we have been given no indication from Merck, who has a representative on our board of directors, that Merck plans to exercise its termination right under the agreement, no assurance can be provided that Merck will not exercise its right and terminate the agreement. In addition, in the event that we do not honor our terms of the agreement and provide funds, employees and other resources to support the clinical programs necessary to support the work conducted under the agreement, Merck may claim that the agreement has been breached and attempt to terminate it. Any loss of Merck revenue could have a significant adverse affect on our operating results and the price of our common stock might decline as a result of either the adverse impact on our net sales or the loss of investor confidence due to any termination by Merck of the agreement.

# In order to be successful, we must retain and motivate key employees. Any failure to do so could adversely affect our business and operating results.

Our future success depends, in large part, upon our ability to retain and motivate our key employees, including James M. Corbett, our chairman, president and chief executive officer, and key managerial, research and development, and sales and marketing personnel. Mr. Corbett's continuation with us is integral to our future success, based on his significant expertise and knowledge of our business and products. Although we have key person insurance with respect to Mr. Corbett, any loss or interruption of the services of Mr. Corbett could reduce our ability to effectively manage our operations and implement our strategy. Key employees may depart because of difficulties with change and integration or a desire not to remain with our company. Competition for qualified personnel can be intense. Any loss or interruption of the services of our key personnel or any employee slowdowns, strikes or similar actions could significantly reduce our ability to meet our strategic objectives because it may not be possible for us to find appropriate replacement personnel should the need arise. We also must continue to keep our employees focused on our strategies and goals, which may be difficult due to integration efforts.

## We may require additional capital in the future, which may not be available or may be available only on unfavorable terms. In addition, any equity financings may be dilutive to our stockholders.

We believe that our proposed operating plan can be accomplished without additional financing based on current and projected net sales and expenses, working capital and current and anticipated financing arrangements. However, there can be no assurance that our anticipated net sales or expense projections will be realized. Furthermore, there may be delays in obtaining necessary governmental approvals of products or introducing products to market or other events that may cause our actual cash requirements to exceed those for which we have budgeted. Our capital requirements will depend on many factors, including the amount and timing of our continued losses and our ability to reach profitability, FoxHollow integration costs, expenditures on intellectual property and technologies, the number of clinical trials which we will conduct, new product development and acquisitions. To the extent that our then existing capital, including amounts available under our revolving line of credit, is insufficient to cover any losses and meet these requirements, we will need to raise additional funds through financings or borrowings or curtail our growth and reduce our assets. From time to time, we may also sell certain technology or intellectual property having a development timeline or development cost that is inconsistent with our investment horizon or which does not adequately complement our existing product portfolio. Any equity or debt financing, if available at all, may be on terms that are not favorable to us. Equity financings could result in dilution to our stockholders, and the securities issued in

future financings as well as in any future acquisitions may have rights, preferences and privileges that are senior to those of our common stock. If our need for capital arises because of continued losses, the occurrence of these losses may make it more difficult for us to raise the necessary capital.

Our business strategy relies on assumptions about the market for our products, which, if incorrect, would adversely affect our business prospects and profitability.

We are focused on the market for endovascular devices used to treat vascular diseases and disorders. We believe that the aging of the general population and increasingly inactive lifestyles will continue and that these trends will increase the need for our products. However, the projected demand for our products could materially differ from actual demand if our assumptions regarding these trends and acceptance of our products by the medical community prove to be incorrect or do not materialize or if drug therapies gain more widespread acceptance as a viable alternative treatment, which in each case, would adversely affect our business and operating results.

Some of our products are emerging technologies or have only recently been introduced into the market. If physicians do not recommend and endorse them or if our working relationships with physicians deteriorate, our products may not be accepted in the marketplace, which would adversely affect our business and operating results.

In order for us to sell our products, physicians must recommend and endorse them. We may not obtain the necessary recommendations or endorsements from physicians. Acceptance of our products depends on educating the medical community as to the distinctive characteristics, perceived benefits, safety, clinical efficacy and cost-effectiveness of our products compared to products of our competitors, and on training physicians in the proper application of our products. We often need to invest in significant training and education of our physician customers to achieve market acceptance of our products with no assurance of success. For example, the future success of our SilverHawk products is dependent upon us educating physicians, and in particular interventional cardiologists, vascular surgeons, as well as general practitioners and other physicians, about screening for peripheral artery disease, or PAD, or about referral opportunities. If we are not successful in obtaining the recommendations or endorsements of physicians for our products, if customers prefer our competitors' products or if our products otherwise do not gain market acceptance, our business could be adversely affected.

In addition, if we fail to maintain our working relationships with physicians, many of our products may not be developed and marketed consistent with the needs and expectations of professionals who use and support our products. We rely on these professionals to provide us with considerable knowledge and experience regarding our products and the marketing of our products. If we are unable to maintain these strong relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could adversely affect the acceptance of our products in the marketplace and our operating results.

Demand for our SilverHawk product in the United States has decreased in recent quarters due in part to the lack of long-term clinical data regarding the safety and efficacy of the SilverHawk, which in part adversely affected our fourth quarter 2007 operating results. Any failure by us to generate additional demand may continue to adversely affect our operating results. In addition, future long-term data regarding the safety and efficacy of the SilverHawk may not be positive or consistent with data currently available, which would adversely affect SilverHawk's market acceptance and our operating results.

One of the primary reasons we completed the acquisition of FoxHollow was to add FoxHollow's SilverHawk and other products to our broad spectrum of technologically advanced products to treat vascular disease in the peripheral market to allow us to offer a more comprehensive and better integrated set of endovascular products to our customers. At the time of the acquisition, we expected sales of the SilverHawk to represent a significant portion of our future net sales. We believe our future success depends in part on the continued commercial success of the SilverHawk. However, demand for the SilverHawk in the United States has decreased in recent quarters: We believe the decrease in demand has been due in part to sales force

integration challenges, elevated inventory levels of the product at some of our customers, increased competition and perhaps, most importantly, a lack of long-term clinical data regarding the safety and efficacy of the SilverHawk. Such decreased demand for SilverHawk has had an adverse affect on our net sales and any failure by us to generate additional demand will likely adversely affect our future net sales as well as our other operating results.

In light of the decreased demand, we recently retained a third party research firm to help us examine our U.S. atherectomy business. The research firm conducted interviews with a significant number of physicians and sales force representatives and analyzed secondary data to understand factors driving the change in SilverHawk usage and atherectomy procedures. The results of this research confirmed our previously stated belief in the importance of investing in the necessary clinical trials to build the clinical foundation for the SilverHawk and capitalizing on our next generation technologies to expand clinical usage, particularly in treating calcified lesions, total occlusions and longer lesions.

Based on this third party research and our own due diligence, we believe that future demand for our SilverHawk will not increase if physicians are not presented with compelling data from long-term studies of the safety and efficacy of the SilverHawk compared against alternative procedures, such as angioplasty, stenting or bypass grafting and alternative technologies. We intend to conduct a multi-center study in which important factors such as long-term data on the rate of restenosis, or plaque regrowth following the procedure, and the corresponding duration of patency, or openness, of the artery. This study may be expensive and time consuming and there are no assurances that the results will prove favorable for the SilverHawk device. If the results do not meet physicians' expectations, the SilverHawk may not become widely adopted and physicians may recommend alternative treatments for their patients. Other significant factors that physicians will consider include acute safety data on complications that occur during the SilverHawk procedure. If the results obtained from any future clinical studies or clinical or commercial experience indicate that the SilverHawk is not as safe or effective as other treatment options or as prior short-term or long-term data would suggest, market acceptance of the product may continue to suffer and the number of SilverHawk procedures may continue to decrease, which would harm our business. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with the SilverHawk may vary and may not be as favorable, which would also adversely affect the demand for our SilverHawk product.

Other factors that may adversely affect the market acceptance of the SilverHawk include the time required to perform the procedure and the lack of on-board visualization capability. If we do not incorporate certain design improvements to the SilverHawk to respond to these and other physician preferences, we may be unable to generate new customers or retain our existing customers. However, we have limited funds dedicated to research and development; and therefore, we will not be able to pursue all of these suggested design changes. A continued decrease in SilverHawk procedures and any failure by us to generate additional demand for the SilverHawk will likely adversely affect our future net sales as well as our other operating results.

Our family of self-expanding stents generates a significant portion of our net sales. Accordingly, if sales of these products were to decline, our operating results and business prospects would be adversely affected.

Our self-expanding stents generates a significant portion of our net sales. During 2007, our self-expanding stents generated approximately 26% of our net sales. While the percentage of net sales for our self-expanding stents likely will decrease in future periods as a result of our acquisition of FoxHollow and presumably an expected increase in net sales of our atherectomy products, nonetheless, a decline in net sales from our self-expanding stents and products often sold together with such stents as a result of regulatory, intellectual property or any other reason would negatively impact our operating results and could also negatively impact our product development activities and therefore our business prospects.

Our future success depends in part on the introduction of new products. Accordingly, any failure to develop and market new products in a timely fashion that are accepted by the marketplace could adversely affect our business and operating results.

We are continually engaged in product development and improvement programs. One of the potential benefits of our acquisition of FoxHollow is that we may have improved cash flow, which should create added resources to fund ongoing, focused research and development programs, future technology innovations and clinical studies to drive the introduction of new products. The introduction of new products represents a significant component of our growth strategy. However, the endovascular device market is highly competitive and designs change often to adjust to patent constraints and to changing market preferences. Therefore, product life cycles are relatively short. If we do not introduce new products and technologies, or if our new products and technologies are not accepted by the physicians who use them or the payors who reimburse the costs of the procedures performed with them, or if there are any delays in our introduction of new products, we may not be successful and our business and operating results would suffer.

We plan to introduce additional products during 2008 which we expect to result in additional net sales. We may experience delays in any phase of a product launch, including during research and development, clinical trials, regulatory approvals, manufacturing, marketing and the education process. Many of our clinical trials have durations of several years and it is possible that competing therapies, such as drug therapies, may be introduced while our products are still undergoing clinical trials. In addition, the suppliers of products that we do not manufacture can suffer delays, which could cause delays in our product introductions. New products and technologies introduced by competitors may reach the market earlier, may be more effective or less expensive than our products or render our products obsolete, all of which would harm our business and operating results.

A number of our proposed products are in the early stages of development and some are in clinical trials. If the development of these products is not successfully completed or if these trials are unsuccessful, or if the U.S. Food and Drug Administration, or FDA, or other regulatory agencies require additional trials to be conducted, these products may not be commercialized and our business prospects may suffer.

Several of our products are in the early stages of development. Some only recently emerged from clinical trials and others have not yet reached the clinical trial stage. Our ability to market our products in the United States and abroad depends upon our ability to demonstrate the safety, and in the case of the United States, efficacy, of our products with clinical data to support our requests for regulatory approval. Our products may not be found to be safe and, where required, effective in clinical trials and may not ultimately be approved for marketing by U.S. or foreign regulatory authorities. Our failure to develop safe and effective products that are approved for sale on a timely basis would have a negative impact on our net sales.

Our current and anticipated trials for 2008 include the CREATE Post Approval Study (U.S.), DURABILITY I (Europe) Trial, DURABILITY II Trail (U.S.), the PROVE-IT Trial (U.S.), PROPSPERO (Europe), the RockHawk SpiderFX Trial (U.S.), the SilverHawk Post Approval Study (U.S.), the Solitaire Stent Flow Restoration Trial, the Solitaire SD Study and the Axium Post Market and Expanded Approvals Trial. There is no assurance that we will be successful in achieving the endpoints in these trials or, if we do, that the FDA or other regulatory agencies will approve the devices for sale without the need for additional clinical trial data to demonstrate safety and efficacy. Some of the products for which we are currently conducting trials are already approved for sale outside of the United States. As a result, while our trials are ongoing, unfavorable data may arise in connection with usage of our products outside the United States which could adversely impact the approval of such products in the United States. Conversely, unfavorable data from clinical trials in the United States may adversely impact sales of our products outside of the United States.

We continually evaluate the potential financial benefits and costs of clinical trials and the products being evaluated in them. If we determine that the costs associated with obtaining regulatory approval of a product exceed the potential financial benefits of that product or if the projected development timeline is inconsistent with our investment horizon, we may choose to stop a clinical trial and/or the development of a product.

Our future success depends in part on our ability to sell SilverHawk and our other products internationally. There are risks inherent in operating internationally and selling and shipping our products and purchasing our components internationally, which may adversely impact our net sales, operating results and financial condition.

One of the strategic rationales for our acquisition of FoxHollow was to leverage our strong international presence to increase sales of SilverHawk and other products. For the year ended December 31, 2007 and 2006, 38% and 40%, respectively, of our net sales were derived from our international operations. We expect to continue to derive a significant portion of our net sales from operations in international markets. Our international distribution system consisted of seven direct sales offices and approximately 48 stocking distribution partners as of December 31, 2007. In addition, we purchase some of our components and products from international suppliers.

The sale and shipping of our products and services across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade regulations. Compliance with such regulations is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, laws restricting business with suspected terrorists and anti-boycott laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities.

In addition, many of the countries in which we sell our products are, to some degree, subject to political, economic and/or social instability. Our international sales operations expose us and our representatives, agents and distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- the imposition of additional U.S. and foreign governmental controls or regulations;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. and/or international sanctions against a country, company, person or entity with whom the company does business that would restrict or prohibit continued business with the sanctioned country, company, person or entity;
- · economic instability:
- a shortage of high-quality sales people and distributors;
- loss of any key personnel that possess proprietary knowledge, or who are otherwise important to our success in certain international markets;
- changes in third-party reimbursement policies that may require some of the patients who receive our
  products to directly absorb medical costs or that may necessitate the reduction of the selling prices of
  our products;
- · changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
- pricing pressure that we may experience internationally;
- laws and business practices favoring local companies;

- · significantly longer payment cycles;
- · difficulties in maintaining consistency with our internal guidelines;
- · difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- · difficulties in enforcing or defending intellectual property rights; and
- exposure to different legal and political standards due to our conducting business in over 50 countries.

No assurance can be given that one or more of the factors will not harm our business. Any material decrease in our international sales would adversely impact our net sales, operating results and financial condition. Our international sales are predominately in Europe. In Europe, health care regulation and reimbursement for medical devices vary significantly from country to country. This changing environment could adversely affect our ability to sell our products in some European countries.

# Fluctuations in foreign currency exchange rates could result in declines in our reported net sales and earnings.

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies could adversely affect our financial results. Approximately 27% and 29% of our net sales during the year ended December 31, 2007 and 2006, respectively, were denominated in foreign currencies. We expect that foreign currencies will continue to represent a significant percentage of our net sales in the future. Approximately 76% and 71% of our net sales denominated in foreign currencies during the year ended December 31, 2007 and 2006, respectively, were derived from European Union countries and were denominated in the Euro. Additionally, we have significant intercompany receivables from our foreign subsidiaries, which are denominated in foreign currencies, principally the Euro and the Yen. Our principal exchange rate risks therefore exist between the U.S. dollar and the Euro and between the U.S. dollar and the Yen. Our international net sales were favorably affected by the impact of foreign currency fluctuations totaling \$6.0 million during the year ended December 31, 2007 and favorably affected by \$443,000 during the year ended December 31, 2006. We cannot assure you that we will benefit from the impact of foreign currency fluctuations in the future and foreign currency fluctuations in the future may adversely affect our net sales and earnings. At present, we do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. If we engage in hedging activities in the future, such activities involve risk and may not limit our underlying exposure from currency fluctuations or minimize our net sales and earnings volatility associated with foreign currency exchange rate changes.

# If third parties claim that we infringe upon their intellectual property rights, we may incur liabilities and costs and may have to redesign or discontinue selling the affected product.

The medical device industry is litigious with respect to patents and other intellectual property rights. Companies operating in our industry routinely seek patent protection for their product designs, and many of our principal competitors have large patent portfolios. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. We face the risk of claims that we have infringed on third parties' intellectual property rights.

We are aware of patents held by Abbott Laboratories that may be asserted against our FoxHollow subsidiary in litigation that could be costly and limit our ability to sell the SilverHawk or other products. One of FoxHollow's founders, John B. Simpson, Ph.D., M.D. founded a company prior to founding FoxHollow that developed an atherectomy device that is currently sold by Abbott, and he is a listed inventor on several patents covering that device. Abbott's device is currently marketed and sold for use in coronary arteries. Although we are not currently aware of any claims Abbott has made or intends to make against FoxHollow, because of a doctrine known as "assignor estoppel," if any of Dr. Simpson's earlier patents are asserted against FoxHollow by Abbott, we may be prevented from asserting an invalidity defense regarding those patents, and our defense may be compromised. Abbott has significantly greater financial resources than us to pursue patent litigation and could assert these patent families against us at any time. Any adverse determinations in such litigation

could prevent us from manufacturing or selling our SilverHawk or other products, which would have a significant adverse impact on our business.

Prior to launching major new products in our key markets, we normally evaluate existing intellectual property rights. However, our competitors may also have filed for patent protection which is not as yet a matter of public knowledge or claim trademark rights that have not been revealed through our availability searches. Our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement, even those without merit, could:

- be expensive and time consuming to defend;
- result in us being required to pay significant damages to third parties;
- · cause us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products, if feasible;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third party's intellectual property, which agreements may not be available on terms acceptable to us or at all;
- divert the attention of our management; or
- result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

In addition, new patents obtained by our competitors could threaten a product's continued life in the market even after it has already been introduced.

We are currently a party to a number of intellectual property claims, which are costly to defend and the resolution of which could have a material adverse effect on our business and results of operations.

We are a party to a patent infringement lawsuit with Boston Scientific pursuant to which Boston Scientific claims, among other things, that some of our products, including our SpiderRX Embolic Protection Device, infringes certain of Boston Scientific's patents and our misappropriation of trade secrets. We are also a party to several legal patent infringement actions in the United States and Europe related to our Sapphire coils. Although we have recently entered into agreements in principle with the parties to these matters to settle them, such matters will not be finally resolved until we have entered into final and binding written settlement agreements with the parties. We cannot assure you that we will be able to enter into such written agreements. These litigation matters have been very costly to defend and if we are not able to enter-into written settlement agreements with the parties, we will be forced to continue to defend the litigation, which will continue to adversely affect our operating results and the resolution of which could adversely affect our business, financial condition and operating results.

If our patents and other intellectual property rights do not adequately protect our products, we may lose market share to our competitors, which would harm our business.

Our future success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright and trademark laws and nondisclosure, confidentiality and other contractual arrangements to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. In addition, we cannot be assured that any of our pending patent applications will result in the issuance of a patent to us. The United States Patent and Trademark Office, or PTO, may deny or require significant narrowing of claims in our pending patent applications, and patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. We could also incur substantial costs in proceedings before the PTO. These proceedings could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. Our issued patents and those that may

be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products. Litigation may also be necessary to enforce patent rights we hold or to protect trade secrets or techniques we own. Intellectual property litigation is costly and may adversely affect our operating results. Although we have taken steps to protect our intellectual property and proprietary technology, there is no assurance that third parties will not be able to design around our patents. We also rely on unpatented proprietary technology. We cannot assure you that we will be able to meaningfully protect all of our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our unpatented proprietary technology. We seek to protect our know-how and other unpatented proprietary technology, in part with confidentiality agreements and intellectual property assignment agreements with our employees, independent distributors and consultants. However, such agreements may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event that our competitors discover or independently develop similar or identical designs or other proprietary information. In addition, we rely on the use of registered trademarks with respect to the brand names of some of our products. We also rely on common law trademark protection for some brand names, which are not protected to the same extent as our rights in the use of our registered trademarks.

Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. For example, foreign countries generally do not allow patents to cover methods for performing surgical procedures. If we cannot adequately protect our intellectual property rights in these foreign countries, our competitors may be able to compete more directly with us, which could adversely affect our competitive position and business.

We also hold licenses from third parties that are necessary to use certain technologies used in the design and manufacturing of some of our products. The loss of such licenses would prevent us from manufacturing, marketing and selling these products, which could harm our business and operating results.

We manufacture our products at single locations. Any disruption in these manufacturing facilities, any patent infringement claims with respect to our manufacturing process or otherwise any inability to manufacture a sufficient number of our products to meet demand could adversely affect our business and operating results.

We rely on our manufacturing facilities in Plymouth, Minnesota and in Irvine and Redwood City, California. We are in the process of consolidating the production of our Rinspirator product into our Redwood City manufacturing facility. Equipment qualification, process development and process validations are complete and we are awaiting the necessary regulatory approval to resume production in Redwood City. During this transition, we may experience difficulties that could impact our ability to meet the demand for the Rinspirator products, which could adversely affect our operating results.

Any damage or destruction to our facilities and the manufacturing equipment we use to produce our products would be difficult to replace and could require substantial lead-time to repair or replace. Our facilities may be affected by natural or man-made disasters. In the event that one of our facilities was affected by a disaster, we would be forced to rely on third-party manufacturers if we could not shift production to our other manufacturing facilities. In the case of a device with a premarket approval application, we might in such event be required to obtain prior FDA or notified body approval of an alternate manufacturing facility, which could delay or prevent our marketing of the affected product until such approval is obtained. Although we believe that we possess adequate insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. It is also possible that one of our competitors could claim that our manufacturing process violates an existing patent. If we were unsuccessful in defending such a claim, we might be forced to stop production at one of our manufacturing facilities in the United States and to seek alternative facilities. Even if we were able to identify such alternative facilities, we might incur additional costs and experience a disruption in the supply of our products until those facilities are available. Any disruption in our manufacturing capacity could have an adverse impact on our ability to produce sufficient

inventory of our products or may require us to incur additional expenses in order to produce sufficient inventory, and therefore would adversely affect our net sales and operating results.

We have limited experience in manufacturing our products in commercial quantities and therefore may encounter unforeseen situations that could result in delays or shortfalls. Manufacturers often experience difficulties in increasing production, including problems with production yields and quality control and assurance. In June 2004, FoxHollow initiated a voluntary recall of two lots of the SilverHawk due to the possibility of improper sterilization at one of two approved sterilization facilities. Any disruption or delay at our manufacturing facilities, any inability to accurately predict the number of products to manufacture or to expand our manufacturing capabilities if necessary could impair our ability to meet the demand of our customers and these customers may cancel orders or purchase products from our competitors, which could adversely affect our business and operating results.

Our dependence on key suppliers puts us at risk of interruptions in the availability of our products, which could reduce our net sales and adversely affect our operating results. In addition, increases in prices for raw materials and components used in our products could adversely affect our operating results.

We rely on a limited number of suppliers for certain raw materials and components used in our products. For reasons of quality assurance, cost effectiveness or availability, we procure certain raw materials and components from sole and limited source suppliers. We generally acquire such raw materials and components through purchase orders placed in the ordinary course of business, and as a result we do not have a significant inventory of these materials and components and do not have any guaranteed or contractual supply arrangements with many of these suppliers. In addition, we also rely on independent contract manufacturers for some of our products. Independent manufacturers have possession of, and in some cases hold title to, molds for certain manufactured components of our products. Our dependence on third-party suppliers involves several risks, including limited control over pricing, availability, quality and delivery schedules, as well as manufacturing yields and costs. Suppliers of raw materials and components may decide, or be required, for reasons beyond our control to cease supplying raw materials and components to us or to raise their prices. Shortages of raw materials, quality control problems, production capacity constraints or delays by our contract manufacturers could negatively affect our ability to meet our production obligations and result in increased prices for affected parts. Any such shortage, constraint or delay may result in delays in shipments of our products or components, which could adversely affect our net sales and operating results. Increases in prices for raw materials and components used in our products could also adversely affect our operating results.

In addition, the FDA and foreign regulators may require additional testing of any raw materials or components from new suppliers prior to our use of these materials or components. In the case of a device with a premarket approval application, we may be required to obtain prior FDA approval of a new supplier, which could delay or prevent our access or use of such raw materials or components or our marketing of affected products until such approval is granted. In the case of a device with clearance under section 510(k) of the Federal Food, Drug and Cosmetic Act, referred to as a 510(k), We may be required to submit a new 510(k) if a change in a raw material or component supplier results in a change in a material or component supplied that is not within the 510(k) cleared device specifications. If we need to establish additional or replacement suppliers for some of these components, our access to the components might be delayed while we qualify such suppliers and obtain any necessary FDA approvals. Our suppliers of finished goods also are subject to regulatory inspection and scrutiny. Any adverse regulatory finding or action against those suppliers could impact their ability to supply us raw materials and components for our products.

Significant and unexpected claims under our EverFlex self-expanding stent worldwide fracture-free guarantee program in excess of our reserves could significantly harm our business, operating results and financial condition.

Beginning in October 2006, we began providing a worldwide fracture-free guarantee as part of our marketing and advertising strategy for our EverFlex self-expanding stents. In the event that an EverFlex self-expanding stent should fracture within two years of implantation, we have agreed to provide a free replacement product to the medical facility, subject to the terms and conditions of the program. Although we

have tested our EverFlex self-expanding stents in rigorous simulated fatigue testing, we commercially launched our EverFlex self-expanding stents on a worldwide basis in early March 2006 and, therefore, in only some cases, have two years of commercial data on which to base our expected claim rates under the program. We may receive significant and unexpected claims under this guarantee program that could exceed the amount of our reserves for the program. Significant claims in excess of our program reserves could significantly harm our business, operating results and financial condition.

Our inability to successfully grow through future acquisitions, our failure to integrate any acquired businesses successfully into our existing operations or our discovery of previously undisclosed liabilities could negatively affect our business and operating results.

In order to build our core technology platforms, we have acquired several businesses since our inception. In October 2007, we completed our acquisition of FoxHollow. In September 2006, FoxHollow acquired Kerberos Proximal Solutions, Inc. In January 2006, we acquired the outstanding shares of Micro Therapeutics, Inc. that we did not already own. We expect to continue to actively pursue additional acquisitions of, investments in or alliances with, other companies and businesses in the future as a component of our business strategy. Our ability to grow through future acquisitions, investments and alliances will depend upon our ability to identify, negotiate, complete and integrate attractive candidates on favorable terms and to obtain any necessary financing. Our inability to complete one or more acquisitions, investments or alliances could impair our ability to develop our product lines and to compete against many industry participants, many of whom have product lines broader than ours. Acquisitions, investments and alliances, including our acquisition of FoxHollow and our and FoxHollow's previous acquisitions, involve risks, including:

- · difficulties in integrating any acquired companies, personnel and products into our existing business;
- delays in realizing projected efficiencies, cost savings, revenue synergies and other benefits of the acquired company or products;
- inaccurate assessment of undisclosed, contingent or other liabilities or problems; ...
- diversion of our management's time and attention from other business concerns;
- · limited or no direct prior experience in new markets or countries we may enter;
- · higher costs of integration than we anticipated; or
- difficulties in retaining key employees of the acquired business who are necessary to manage these
  acquisitions.

For example, we had difficulties integrating our and FoxHollow's U.S. peripheral vascular sales forces. In addition, our acquisition of FoxHollow resulted in our need to defend additional litigation, both existing litigation of FoxHollow and additional litigation of FoxHollow that was commenced or threatened after announcement of our proposed acquisition of FoxHollow. After our announcement of our proposed acquisition of FoxHollow, FoxHollow received a letter from counsel for the shareholder representatives of Kerberos alleging that FoxHollow has not used commercially reasonable efforts to market, promote, sell and distribute Kerberos' Rinspirator products, as required under the agreement and plan of merger between FoxHollow and Kerberos.

In addition, an acquisition, investment or alliance could materially impair our operating results and liquidity by causing us to incur debt or reallocate amounts of capital from other operating initiatives or requiring us to amortize transaction expenses and acquired assets, incur non-recurring charges as a result of incorrect estimates made in the accounting for such transactions or record asset impairment charges. We may also discover deficiencies in internal controls, data adequacy and integrity, product quality, regulatory compliance and product liabilities which we did not uncover prior to our acquisition of such businesses, which could result in us becoming subject to penalties or other liabilities. Any difficulties in the integration of acquired businesses or unexpected penalties or liabilities in connection with such businesses could have a material adverse effect on our operating results and financial condition. These risks could be heightened if we complete several acquisitions within a relatively short period of time.

Charges resulting from the application of the purchase method of accounting relating to our acquisition of FoxHollow may adversely affect the market value of our common stock following the acquisition.

In accordance with U.S. GAAP, we are considered the acquirer of FoxHollow for accounting purposes. We have accounted for the acquisition using the purchase method of accounting, which has resulted and may continue to result in charges to our earnings, if any, that could adversely affect the market value of our common stock. Under the purchase method of accounting, we have allocated the total purchase price to the assets acquired and liabilities assumed from FoxHollow based on their fair values as of October 4, 2007, the date of the completion of the acquisition, and have recorded any excess of the purchase price over those fair values as goodwill. We have incurred and will continue to incur amortization expense over the useful lives of amortizable intangible assets acquired in connection with the acquisition. In addition, to the extent the value of goodwill becomes impaired, we may be required to incur material charges relating to the impairment of that asset. These amortization and potential impairment charges could have a material impact on our results of operations.

We have incurred and expect to continue to incur significant transaction and integration-related costs in connection with our acquisition of FoxHollow and the integration of FoxHollow's operations into ours.

We have incurred and expect to continue to incur a number of non-recurring costs associated with our acquisition of FoxHollow and integrating FoxHollow's operations with ours. The substantial majority of non-recurring expenses resulting from the acquisition will be comprised of transaction costs related to the acquisition, employment-related costs and facilities and systems consolidation costs. Although we currently estimate one-time transaction and integration-related cash payments relating to the acquisition to be between approximately \$71 million to \$73 million, this estimate may prove to be inaccurate and additional unanticipated costs may be incurred in the integration of the two companies' businesses. Although we expect that the elimination of duplicative costs, as well as the realization of other efficiencies related to the integration of the businesses should allow us to offset incremental transaction and integration-related costs over time, this net benefit may not be achieved in the near term, or at all.

The demand for our products, the prices which customers and patients are willing to pay for our products and the number of procedures performed using our products depend upon the ability of our customers and patients to obtain sufficient third party reimbursement for their purchases of our products.

Sales of our products depend in part on sufficient reimbursement by governmental and private health care payors to our physician customers or their patients for the purchase and use of our products. In the United States, health care providers that purchase our products generally rely on third-party payors, principally federal Medicare, state Medicaid and private health insurance plans, to pay for all or a portion of the cost of endovascular procedures. Reimbursement systems in international markets vary significantly by country, and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis and can take up to 18 months or longer. Many international markets have government-managed health care systems that govern reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. Any delays in obtaining, or an inability to obtain, reimbursement approvals or sufficient reimbursement for our products could significantly affect the acceptance of our products and have a material adverse effect on our business. In addition, if the reimbursement policies of domestic or foreign governmental or private health care payors were to change, our customers would likely change their purchasing patterns and/or the frequency of their purchases of the affected products. Additionally, payors continue to review their coverage policies carefully for existing and new therapies and can, without notice, deny coverage for treatments that include the use of our products. Our business would be negatively impacted to the extent any such changes reduce reimbursement for our products.

Healthcare costs have risen significantly over the past decade. There have been and may continue to be proposals by legislators, regulators and third-party payors to keep these costs down. The continuing efforts of governments, insurance companies and other payors of healthcare costs to contain or reduce these costs,

combined with closer scrutiny of such costs, could lead to patients being unable to obtain approval for payment from these third-party payors. The cost containment measures that healthcare providers are instituting both in the United States and internationally could harm our business. Some health care providers in the United States have adopted or are considering a managed care system in which the providers contract to provide comprehensive health care for a fixed cost per person. Health care providers may attempt to control costs by authorizing fewer elective surgical procedures or by requiring the use of the least expensive devices possible, which could adversely affect the demand for our products or the price at which we can sell our products.

We also sell a number of our products to physician customers who may elect to use these products in ways that are not within the scope of the approval or clearance given by the FDA, often referred to as "off-label" use. In the event that governmental or private health care payors limit reimbursement for products used off-label, sales of our products and our business would be materially adversely affected.

Consolidation in the healthcare industry could lead to demands for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or operating results.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for some of our hospital customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances, which may increase competition, exert further downward pressure on the prices of their products and may adversely impact our business, financial condition or operating results.

Our products and our product development and marketing activities are subject to extensive regulation as a result of which we may not be able to obtain required regulatory approvals for our products in a cost-effective manner or at all, which could adversely affect our business and operating results.

The production and marketing of our products and our ongoing research and development, preclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. U.S. and foreign regulations applicable to medical devices are wide-ranging and govern, among other things, the development, testing, marketing and premarket review of new medical devices, in addition to regulating manufacturing practices, reporting, advertising, exporting, labeling and record keeping procedures. We are required to obtain FDA approval or clearance before we can market our products in the United States and certain foreign countries. The regulatory process requires significant time, effort and expenditures to bring products to market, and it is possible that our products will not be approved for sale. Even if regulatory approval or clearance of a product is granted, it may not be granted within the timeframe that we expect, which could have an adverse effect on our operating results and financial condition. In addition, even if regulatory approval or clearance of a product is granted, the approval or clearance could limit the uses for which the product may be labeled and promoted, which may limit the market for our products. Even after a product is approved or cleared by the FDA, we may have ongoing responsibilities under FDA regulations, non-compliance of which could result in the subsequent withdrawal of such approvals or clearances, or such approvals or clearances could be withdrawn due to the occurrence of unforeseen problems following initial approval. We also are subject to medical device reporting regulations that require us to report to the FDA if any of our products causes or contributes to a death or serious injury or if a malfunction were it to occur might cause or contribute to a death or serious injury. Any failure to obtain regulatory approvals or clearances on a timely basis or the subsequent withdrawal of such approvals or

clearances could prevent us from successfully marketing our products, which could adversely affect our business and operating results.

Our failure to comply with applicable regulatory requirements could result in governmental agencies:

- · imposing fines and penalties on us;
- preventing us from manufacturing or selling our products;
- · bringing civil or criminal charges against us;
- delaying the introduction of our new products into the market;
- suspending any ongoing clinical trials;
- · issuing an injunction preventing us from manufacturing or selling our products or imposing restrictions;
- recalling or seizing our products; or
- · withdrawing or denying approvals or clearances for our products.

Our failure to comply with applicable regulatory requirements may also result in us not being able to meet the demands of our customers and our customers canceling orders or purchasing products from our competitors, which could adversely affect our business and operating results.

When required, with respect to the products we market in the United States, we have obtained premarket notification clearance under section 510(k), but do not believe certain modifications we have made to our products require us to submit new 510(k) notifications. However, if the FDA disagrees with us and requires us to submit a new 510(k) notification for modifications to our existing products, we may be subject to enforcement actions by the FDA and be required to stop marketing the products while the FDA reviews the 510(k) notification. If the FDA requires us to go through a lengthier, more rigorous examination than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain premarket approval application process. Products that are approved through a premarket approval application generally need FDA approval before they can be modified. If we fail to submit changes to products developed under IDEs or premarket approval applications in a timely or adequate manner, we may become subject to regulatory actions.

In addition, we market our products in select countries outside of the United States. In order to market our products abroad, we are required to obtain separate regulatory approvals and comply with numerous requirements. If additional regulatory requirements are implemented in the foreign countries in which we sell our products, the cost of developing or selling our products may increase. For example, recent regulations in Japan have increased the regulatory and quality assurance requirements in order to obtain and maintain regulatory approval to market our products in Japan. These regulations resulted in higher costs and delays in securing approval to market our products in Japan. We depend on our distributors outside the United States in seeking regulatory approval to market our devices in other countries and we therefore are dependent on persons outside of our direct control to secure such approvals. For example, we are highly dependent on distributors in emerging markets such as China and Brazil for regulatory submissions and approvals and do not have direct access to health care agencies in those markets to ensure timely regulatory approvals or prompt resolution of regulatory or compliance matters. If our distributors fail to obtain the required approvals or do not do so in a timely manner, our net sales from our international operations and our operating results may be adversely affected.

Our marketing activities are subject to regulation regarding the promotion of "off-label" uses, which restrict our ability to market our products and could adversely affect our growth. Any off-label use of our products may result in injuries that could lead to product liability claims against us.

We sell a number of our products to physicians who may elect to use the products in ways that are not within the scope of the approval or clearance given by the FDA or for other than FDA-approved indications,

often referred to as "off-label" use. While off-label uses of medical devices are common and the FDA does not regulate physicians' choice of treatments, the FDA does restrict a manufacturer's communications regarding such off-label use. Such laws and regulations prohibiting the promotion of products for off-label use restrict our ability to market our products and could adversely affect our growth. Although we have strict policies against the unlawful promotion of products for off-label use and we train our employees on these policies, it is possible that one or more of our employees will not follow the policies, or that regulations would change in a way that may hinder our ability to sell such products or make it more costly to do so, which could expose us to financial penalties as well as loss of approval to market and sell the affected products. If physicians cease or lessen their use of products for other than FDA-approved indications, sales of our products could decline, which could materially adversely affect our net sales and operating results. In addition, it is our understanding that certain biliary stent manufacturers recently have become involved in civil investigations by the U.S. Department of Justice alleging that they have improperly promoted their biliary stents for off-label uses. Although we have received no notice of any such investigation involving the sales practices of our biliary stents, no assurance can be provided that we will not become the subject of such an investigation, which could adversely affect our business and stock price.

If we want to market any of our products for use in ways for which they are not currently approved, we may need to conduct clinical trials and obtain approval from appropriate regulatory bodies, which could be time-consuming and costly. For example, our SilverHawk received FDA approval for the treatment of atherosclerosis in the peripheral vasculature, which restricts our ability to market or advertise the SilverHawk for any specific indication within the peripheral arteries. Off-label use of the SilverHawk outside the peripheral vasculature, in coronary and carotid arteries, has occurred and is likely to continue. In addition, off-label use for treatment of in-stent restenosis has occurred and is likely to continue. We are not able to promote or advertise the SilverHawk for off-label uses or make comparative claims regarding the use of the SilverHawk against any alternative treatments without conducting head-to-head comparative clinical studies, which would be expensive and time consuming. If we desire to market the SilverHawk in the United States for use in coronary or carotid arteries, we will need to conduct further clinical trials and obtain premarket approval from the FDA. Although FoxHollow previously began a clinical trial in support of FDA approval for use of the SilverHawk in the coronary arteries, it voluntarily halted enrollment so that it could incorporate safety and design improvements into the coronary product. To market the SilverHawk in the United States for this use, we must successfully complete a clinical trial, submit a premarket approval application to the FDA and obtain premarket approval. No assurance can be given that the results of such a trial will adequately demonstrate the safety and efficacy of the SilverHawk for use in coronary arteries.

Off-label use of our product may not be safe or effective and may result in unfavorable outcomes to patients, resulting in potential liability to us. For example, the use or misuse of the SilverHawk in the peripheral and coronary arteries has in the past resulted, and may in the future result, in complications, including damage to the treated artery, internal bleeding, limb loss and death, potentially leading to a product liability claim. Penalties or liabilities stemming from off-label use could have a material adverse effect on our operating results.

If we or others identify side effects after any of our products are on the market, we may be required to withdraw our products from the market, which would hinder or preclude our ability to generate net sales.

As part of our post-market regulatory responsibilities for our products classified as medical devices, we are required to report all serious injuries or deaths involving our products, and any malfunctions where a serious injury or death would be likely if the malfunction were to recur. If we or others identify side effects after any of our products are on the market:

- · regulatory authorities may withdraw their approvals;
- · we may be required to reformulate our products; .
- we may have to recall the affected products from the market and may not be able to reintroduce them onto the market;

- · our reputation in the marketplace may suffer; and
- we may become the target of lawsuits, including class action suits.

Any of these events could harm or prevent sales of the affected products or could substantially increase the costs and expenses of commercializing or marketing these products.

# Our manufacturing facilities are subject to extensive governmental regulation with which compliance is costly and which expose us to penalties for non-compliance.

We and our third party manufacturers are required to register with the FDA as device manufacturers and as a result, we and our third party manufacturers are subject to periodic inspections by the FDA for compliance with the FDA's Quality System Regulation, or QSR, requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, the federal Medical Device Reporting regulations require us and our third party manufacturers to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. We are also subject to similar state requirements and licenses. In the European Community, we are required to maintain certain International Organization for Standardization, or ISO, certifications in order to sell products and we are required to undergo periodic inspections by notified bodies to obtain and maintain these certifications. If we or our manufacturers fail to adhere to QSR or ISO requirements, this could delay production of our products and lead to fines, difficulties and delays in obtaining regulatory approvals and clearances, the withdrawal of regulatory approvals and clearances, recalls or other consequences, which could in turn have a material adverse effect on our financial condition and operating results. In addition, regulatory agencies may not agree with the extent or speed of corrective actions relating to product or manufacturing problems.

## Our operations are subject to environmental, health and safety, and other laws and regulations, with which compliance is costly and which expose us to penalties for non-compliance.

Our business, properties and products are subject to foreign, federal, state and local laws and regulations relating to the protection of the environment, natural resources and worker health and safety and the use, management, storage, and disposal of hazardous substances, wastes, and other regulated materials. Because we operate real property, various environmental laws also may impose liability on us for the costs of cleaning up and responding to hazardous substances that may have been released on our property, including releases unknown to us. FoxHollow's leased Redwood City facility sits on property formerly occupied by Rohm & Haas and Occidental Chemical Company and contains residual contamination in soil and groundwater from these past industrial operations. Rohm & Haas and Occidental Chemical Company previously performed soil remediation on the property under the supervision of the California Regional Water Quality Control Board. Rohm & Haas has indemnified the owner of the facility and its tenants against costs associated with the residual contamination, but there can be no assurance that this indemnification will be adequate to cover the extent of the liability. These environmental laws and regulations also could require us to pay for environmental remediation and response costs at third-party locations where we disposed of or recycled hazardous substances. The costs of complying with these various environmental requirements, as they now exist or may be altered in the future, could adversely affect our financial condition and operating results.

### Our quarterly operating and financial results may fluctuate in future periods.

Our quarterly operating and financial results may fluctuate from period to period. Some of the factors that may influence our quarterly operating results include:

- the seasonality of our product sales, which typically results in higher demand in our fourth fiscal quarter and lower sales volumes in our third fiscal quarter;
- the mix of our products sold;

- · demand for, and pricing of, our products;
- timing of or failure to obtain regulatory approvals for products;
- costs, benefits and timing of new product introductions;
- the timing and extent of promotional pricing or volume discounts;
- the timing of larger orders by customers and the timing of shipment of such orders;
- · field inventory levels;
- · changes in average selling prices;
- · the availability and cost of components and materials; and
- fluctuations in foreign currency exchange rates.

Because of these factors, our operating results in one or more future quarters may fail to meet the expectations of securities analysts or investors, which could cause our stock price to decline significantly.

## We may become obligated to make large milestone payments that are not reflected in our financial statements in certain circumstances, which would negatively impact our cash flows from operations.

Pursuant to the acquisition agreements relating to our purchase of MitraLife and Appriva Medical, Inc. in 2002, we agreed to make additional payments to the sellers of these businesses in the event that we achieve contractually defined milestones. Generally, in each case, these milestone payments become due upon the completion of specific regulatory steps in the product commercialization process. With respect to the MitraLife acquisition, the maximum potential milestone payments totaled \$25 million, and with respect to the Appriva acquisition, the maximum potential milestone payments totaled \$175 million. Although we do not believe that it is likely that these milestone payment obligations became due, or will become due in the future, the former stockholders of Appriva disagree with our position and have brought litigation against us making a claim for such payments and it is possible that the former stockholders of MitraLife could also disagree with our position and make a claim for such payments. Pursuant to the acquisition agreement relating to FoxHollow's purchase of Kerberos Proximal Solutions, Inc., FoxHollow has agreed to pay certain earnout payments which are capped at \$117 million upon the achievement of contractually defined net sales milestones. On August 20, 2007, FoxHollow received a letter from counsel for the shareholder representatives of Kerberos alleging that FoxHollow has not used commercially reasonable efforts to market, promote, sell and distribute Kerberos' Rinspirator products, as required under the agreement and plan of merger. There can be no assurance that the stockholder representatives of Kerberos will not commence litigation on the alleged claims.

The defense of the outstanding litigation related to our Appriva acquisition and the outstanding claims related to FoxHollow's Kerberos acquisition is, and any such additional dispute with MitraLife would likely be, costly and time-consuming and divert our management's time and attention away from our business. In the event any such milestone payments become due and/or any other damages become payable, our costs would increase correspondingly which would negatively impact our cash flow from operations.

## We rely on independent sales distributors and sales associates to market and sell our products outside of the United States, Canada and Europe.

Our future success outside of the United States, Canada and Europe depends largely upon marketing arrangements with independent sales distributors and sales associates, in particular their sales and service expertise and relationships with the customers in the marketplace. Independent distributors and sales associates may terminate their relationship with us, or devote insufficient sales efforts to our products. We are not able to control our independent distributors and they may not be successful in implementing our marketing plans. In addition, many of our independent distributors outside of the United States, Canada and Europe initially obtain and maintain foreign regulatory approval for sale of our products in their respective countries. Our failure to maintain our relationships with our independent distributors and sales associates outside of the United States, Canada and Europe, or our failure to recruit and retain additional skilled independent sales distributors and

sales associates in these locations, could have an adverse effect on our operations. We have experienced turnover with some of our independent distributors in the past that has adversely affected our short-term financial results while we transitioned to new independent distributors. Similar occurrences could happen to us in the future.

If we fail to comply with the U.S. Federal Anti-Kickback Statute and similar state laws, we could be subject to criminal and civil penalties and exclusion from the Medicare, Medicaid and other federal health care programs, which could have a material adverse effect on our business and operating results.

A provision of the Social Security Act, commonly referred to as the Federal Anti-Kickback Statute, prohibits the offer, payment, solicitation or receipt of any form of remuneration in return for referring, ordering, leasing, purchasing or arranging for or recommending the ordering, purchasing or leasing of items or services payable by Medicare, Medicaid or any other federal health care program. The Federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations, and thus are subject to evolving interpretations. In addition, most of the states in which our products are sold have adopted laws similar to the Federal Anti-Kickback Statute, and some of these laws are even broader than the Federal Anti-Kickback Statute in that their prohibitions are not limited to items or services paid for by a federal health care program but, instead, apply regardless of the source of payment. Violations of the Federal Anti-Kickback Statute may result in substantial civil or criminal penalties and exclusion from participation in federal health care programs.

All of our financial relationships with health care providers and others who provide products or services to federal health care program beneficiaries are potentially governed by the Federal Anti-Kickback Statute and similar state laws. While we believe our operations are in material compliance with the Federal Anti-Kickback Statute and similar state laws, no assurance can be given that we will not be subject to investigations or litigation alleging violations of these laws, which could be time-consuming and costly to us and could divert management's attention from operating our business, and which could have a material adverse effect on our business. In addition, if our arrangements were found to violate the Federal Anti-Kickback Statute or similar state laws, we or our officers and employees could be subject to severe criminal and civil penalties, including, for example, exclusion from participation in any federal health care programs, which could have a material adverse effect on our reputation, business and operating results.

If our distribution agreement with Invatec Technology Center GmbH expires or terminates and we are unable to commercially launch on a timely basis our own products to replace the products we currently distribute for Invatec in the United States or if we are unable to enter into a substitute arrangement with another third party or if there is a disruption in the supply of Invatec products that we distribute, our net sales and operating results would be adversely impacted.

We have entered into an agreement with Invatec Technology Center GmbH, or Invatec, an Italian manufacturer of endovascular medical devices to distribute on a non-exclusive basis some of Invatec's branded products throughout the United States. This arrangement provides us with a broad portfolio of commercially competitive products that complement our existing portfolio. The Invatec products that we distribute include the Sailor Plus, Submarine Plus, Admiral Xtreme and Amphirion Deep PTA catheters and the Diver C.E. Thrombus Aspiration Catheter. The term of our agreement with Invatec expires on December 31, 2008, however, we continue to have the right to sell our remaining inventory of Invatec products through June 30, 2008. If the agreement expires or terminates and we are unable to commercially launch on a timely basis our own products to replace the products we currently distribute for Invatec in the United States or if we are unable to enter into a substitute arrangement with another third party, our net sales and operating results would be adversely impacted. In addition, if Invatec is unable to produce enough products to meet our demands, including if Invatec sells its inventory to our competitors rather than to us for marketing under their own brands, we may not be able to meet our customers' demands and our net sales and operating results may suffer.

We are exposed to product liability claims that could have an adverse effect on our business and operating results.

The design, manufacture and sale of medical devices expose us to significant risk of product liability claims, some of which may have a negative impact on our business. Most of our products were developed relatively recently and defects or risks that we have not yet identified may give rise to product liability claims. Our product liability insurance coverage may be inadequate to protect us from any liabilities we may incur or we may not be able to maintain adequate product liability insurance at acceptable rates. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage and it is ultimately determined that we are liable, our business could suffer. Additionally, we could experience a material design defect or manufacturing failure in our products, a quality system failure, other safety issues or heightened regulatory scrutiny that would warrant a recall of some of our products. A recall of our products could also result in increased product liability claims. Further, while we train our physician customers on the proper usage of our products, there can be no assurance that they will implement our instructions accurately. If our products are used incorrectly by our customers, injury may result and this could give rise to product liability claims against us. Even a meritless or unsuccessful product liability claim could harm our reputation in the industry, lead to significant legal fees and could result in the diversion of management's attention from managing our business and may have a negative impact on our business and our operating results. In addition, successful product liability claims against one of our competitors could cause claims to be made against us.

Our net sales could decline significantly if drug-eluting stents become a dominant therapy in the peripheral vascular stent market and we are not able to develop or acquire a drug-eluting stent to market and sell.

The peripheral vascular market is currently comprised exclusively of bare metal, or non drug-eluting, stents. However, there are clinical situations in the periphery in which a drug-eluting stent may demonstrate clinical superiority over bare metal stents. To the extent that our peripheral stent customers seek stents with drug coatings and we do not market and sell a drug-eluting peripheral stent or one that achieves market acceptance, we may not be able to compete as effectively with those of our competitors that are able to develop and sell a drug-eluting stent, and our peripheral stent sales could decline. If our peripheral stent sales were to decline, we could experience a significant decline in sales of affiliated products which are routinely purchased in conjunction with our stents.

We face competition from other companies, many of which have substantially greater resources than us and may be able to more effectively develop, market and sell their products than we can, which could adversely impact our business, net sales and operating results. Consolidation in the medical technology industry would exacerbate these risks.

The markets in which we compete are highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Although our competitors range from small start-up companies to much larger companies, the markets for most of our products, other than our atherectomy products, are dominated by a small number of large companies, including Abbott Laboratories, Boston Scientific Corporation, Cook Incorporated, Cordis Corporation (a Johnson & Johnson company) and Medtronic, Inc. Despite our acquisition of FoxHollow, we are still a much smaller company relative to our primary competitors. Our products compete with other medical devices, including Invatec-manufactured products sold in the United States under other brand names, surgical procedures and pharmaceutical products. A number of the companies in the medical technology industry, including manufacturers of peripheral vascular, cardiovascular and neurovascular products, have substantially greater capital resources, larger customer bases, broader product lines, larger sales forces, greater marketing and management resources, larger research and development staffs and larger facilities than ours and have established reputations and relationships with our target customers, as well as worldwide distribution channels that are more effective than ours. Within the atherectomy market, although we believe our SilverHawk product competes favorably against other competing technologies, surgical procedures and pharmaceutical products, recently introduced atherectomy products or products that will likely be introduced to the market shortly may adversely affect future sales of our SilverHawk product.

Because of the size of the vascular disease market opportunity, competitors and potential competitors have historically dedicated and will continue to dedicate significant resources to aggressively promote their products and develop new and improved products. Our competitors and potential competitors may develop technologies and products that are safer, more effective, easier to use, less expensive or more readily accepted than ours. Their products could make our technology and products obsolete or noncompetitive. None of our customers have long-term purchase agreements with us and may at any time switch to the use of our competitors' products. Our competitors may also be able to achieve more efficient manufacturing and distribution operations than we can and may offer lower prices than we could offer profitably. We expect that as our products mature, we will be able to produce our products in a more cost effective manner and therefore be able to compete more effectively, but it is possible that we may not achieve such cost reductions. Any of these competitive factors could adversely impact our business, net sales and operating results. In addition, the industry has recently experienced some consolidation. For example, during 2007, Hologic, Inc. merged with Cytyc Corporation, Inverness Medical Innovations, Inc. acquired Cholestech Corporation and HemoSense, Inc. and Medtronic, Inc. acquired Kyphon Inc. Consolidation could make the competitive environment even more difficult for smaller companies and exacerbate these risks.

We also compete with other manufacturers of medical devices for clinical sites to conduct human trials. If we are not able to locate clinical sites on a timely or cost-effective basis, this could impede our ability to conduct trials of our products and, therefore, our ability to obtain required regulatory clearance or approval.

We rely on our management information systems for inventory management, distribution and other functions and to maintain our research and development and clinical data. If our information systems fail to adequately perform these functions or if we experience an interruption in their operation, our business and operating results could be adversely affected.

The efficient operation of our business is dependent on our management information systems, on which we rely to effectively manage accounting and financial functions; manage order entry, order fulfillment and inventory replenishment processes; and to maintain research and development and clinical data. The failure of our management information systems to perform as we anticipate could disrupt our business and product development and could result in decreased sales, increased overhead costs, excess inventory and product shortages, causing our business and operating results to suffer. In addition, our management information systems are vulnerable to damage or interruption from:

- earthquake, fire, flood and other natural disasters;
- terrorist attacks and attacks by computer viruses or hackers; and
- · power loss or computer systems, Internet, telecommunications or data network failure.

Any such interruption could adversely affect our business and operating results.

The restrictive covenants in our loan agreement could limit our ability to conduct our business and respond to changing economic and business conditions and may place us at a competitive disadvantage relative to other companies that are subject to fewer restrictions.

Our loan and security agreement with Silicon Valley Bank requires our compliance with a liquidity ratio. Our failure to comply with this financial covenant could adversely affect our financial condition. The loan agreement limits our ability and the ability of certain of our subsidiaries to, among other things:

- transfer all or any part of our business or properties;
- permit or suffer a change in control;
- · merge or consolidate, or acquire any entity;
- engage in any material new line of business;
- · incur additional indebtedness or liens with respect to any of their properties;

- pay dividends or make any other distribution on or purchase of, any of their capital stock;
- · make investments in other companies; or
- · engage in related party transactions,

subject in each case to certain exceptions and limitations. As of December 31, 2007, we had \$10.0 million in outstanding borrowings under the equipment line of credit, no outstanding borrowings under the revolving line of credit and \$2.4 million of outstanding letters of credit issued by Silicon Valley Bank. As of December 31, 2007, our cash, cash equivalents and short-term investments were \$90.8 million. In light of the amount of our cash, cash equivalents and short-term investments and the amounts outstanding under the loan agreement, it is possible that if we needed to we could pay off the outstanding amounts under the loan agreement at this time. However, it is also possible that if we do not generate cash from operations as we anticipate or if we incur significant unanticipated costs that we may need the flexibility provided under our Silicon Valley Bank loan agreement. The restrictive covenants under the loan agreement could limit our ability, and that of certain of our subsidiaries, to obtain future financing, withstand a future downturn in our business or the economy in general or otherwise conduct necessary corporate activities. The financial and restrictive covenants contained in the loan agreement could also adversely affect our ability to respond to changing economic and business conditions and place us at a competitive disadvantage relative to other companies that may be subject to fewer restrictions. Transactions that we may view as important opportunities, such as acquisitions, may be subject to the consent of Silicon Valley Bank, which consent may be withheld or granted subject to conditions specified at the time that may affect the attractiveness or viability of the transaction.

We cannot assure you that we will be able to comply with all of these restrictions and covenants at all times, especially the financial covenant. Our ability to comply with these restrictions and covenants will depend on the success of our business and our operating results and may also be affected by events beyond our control. A breach of any of the restrictions or covenants in the loan agreement by us or certain of our subsidiaries could lead to an event of default under the terms of the credit agreement, notwithstanding our ability to meet the debt service obligations thereunder. Upon the occurrence and during the continuance of an event of default under the loan agreement, Silicon Valley Bank has available a range of remedies customary in these circumstances, including declaring all such debt, together with accrued and unpaid interest thereon, to be due and payable, foreclosing on the assets securing the loan agreement and/or ceasing to provide additional revolving loans or letters of credit, which could have a material adverse effect on us. Although it is possible we could negotiate a waiver with Silicon Valley Bank of an event of default, such a waiver would likely involve significant costs.

## If we become profitable, we cannot assure you that our net operating losses will be available to reduce our tax liability.

Our ability to use, or the amount of, our net operating losses may be limited or reduced. Generally under section 382 of the Code, in the event of an "ownership change" of a company, the company is only allowed to use a limited amount of its net operating losses arising prior to the ownership change for each taxable year thereafter. As a result of prior transactions effected by us and as a result of our acquisition of FoxHollow, our ability to use our and FoxHollow's existing net operating losses to offset U.S. federal taxable income if we become profitable may be subject to substantial limitations. These limitations could potentially result in increased future tax liability for us.

# A substantial portion of our assets consist of goodwill and an impairment in the value of our goodwill would have the effect of decreasing our earnings or increasing our losses.

As of December 31, 2007, goodwill represented \$586.6 million, or 54%, of our total assets. If we are required to record an impairment charge to earnings relating to goodwill, it will have the effect of decreasing our earnings or increasing our losses. The accounting standards on goodwill and other intangible assets require goodwill to be reviewed at least annually for impairment, and do not permit amortization. In the event that impairment is identified, a charge to earnings will be recorded and our stock price may decline as a result.

#### Risks Related to our Common Stock

One of our principal stockholders and its affiliates are able to influence matters requiring stockholder approval and could discourage the purchase of our outstanding shares at a premium.

As of March 3, 2008, Warburg Pincus beneficially owned approximately 29.8% of our outstanding common stock. In addition, under a holders agreement, we are required to nominate and use our best efforts to have elected to our board of directors two persons designated by Warburg, Pincus and certain of its affiliates, which we refer to collectively as the "Warburg Pincus Entities," and Vertical Fund I, L.P. and Vertical Fund II, L.P., which we refer to together as the "Vertical Funds," if the Warburg Pincus Entities, the Vertical Funds and their affiliates collectively beneficially own 20% or more of our common stock. As a result of Warburg Pincus' share ownership and representation on our board of directors, Warburg Pincus is able to influence our affairs and actions, including matters requiring stockholder approval, such as the election of directors and approval of significant corporate transactions. The interests of Warburg Pincus may differ from the interests of our other stockholders. For example, Warburg Pincus could oppose a third party offer to acquire us that the other stockholders might consider attractive, and the third party may not be able or willing to proceed unless Warburg Pincus, as one of our significant stockholders, supports the offer. Warburg Pincus' concentration of ownership may have the effect of delaying, preventing or deterring a change in control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale or merger of our company and may negatively affect the market price of our common stock. Transactions that could be affected by this concentration of ownership include proxy contests, tender offers, mergers or other purchases of common stock that could give our stockholders the opportunity to realize a premium over the then-prevailing market price for shares of our common stock. In such case and in similar situations, our other stockholders may disagree with Warburg Pincus as to whether the action opposed or supported by Warburg Pincus is in the best interest of our stockholders.

## Certain of our principal stockholders may have conflicts of interests with our other stockholders or our company in the future.

Certain of our principal stockholders, including Warburg Pincus, may make investments in companies and from time to time acquire and hold interests in businesses that compete directly or indirectly with us. These other investments may:

- · create competing financial demands on our principal stockholders;
- · create potential conflicts of interest; and
- require efforts consistent with applicable law to keep the other businesses separate from our operations.

These principal stockholders may also pursue acquisition opportunities that may be complementary to our business and, as a result, those acquisition opportunities may not be available to us. Furthermore, these principal stockholders may have an interest in us pursuing acquisitions, divestitures, financings or other transactions that, in their judgment, could enhance their equity investment, even though such transactions might involve risks to our stockholders. In addition, these principal stockholders' rights to vote or dispose of equity interests in us are not subject to restrictions in favor of us other than as may be required by applicable law.

## Our corporate documents and Delaware law contain provisions that could discourage, delay or prevent a change in control of our company.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger or acquisition involving our company that our stockholders may consider favorable. For example, our amended and restated certificate of incorporation authorizes our board of directors to issue up to 100 million shares of "blank check" preferred stock. Without stockholder approval, the board of directors has the authority to attach special rights, including voting and dividend rights, to this preferred stock. With these rights, preferred stockholders could make it more difficult for a third party to acquire our company. In addition, our amended and restated certificate of incorporation provides for a

staggered board of directors, whereby directors serve for three year terms, with approximately one third of the directors coming up for reelection each year. Having a staggered board makes it more difficult for a third party to obtain control of our board of directors through a proxy contest, which may be a necessary step in an acquisition of our company that is not favored by our board of directors.

We are also subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. Under these provisions, if anyone becomes an "interested stockholder," we may not enter into a "business combination" with that person for three years without special approval, which could discourage a third party from making a takeover offer and could delay or prevent a change of control. For purposes of Section 203, "interested stockholder" means, generally, someone owning 15% or more of our outstanding voting stock or an affiliate of our company that owned 15% or more of our outstanding voting stock during the past three years, subject to certain exceptions as described in Section 203. Under one such exception, Warburg Pincus does not constitute an "interested stockholder."

A large percentage of our outstanding common stock is held by insiders, and, as a result, the trading market for the common stock will not be as liquid as the stock of other public companies, and our common stock price could be volatile.

We have approximately 105.2 million shares of common stock outstanding and approximately 34.6% of the shares are beneficially owned by directors, executive officers, principal stockholders and their respective affiliates. Companies with a substantial amount of stock held by insiders can be subject to a more volatile stock price. Fluctuations in the price of our common stock could be significant and will likely be impacted by a number of factors, such as:

- the introduction of new products or product enhancements by us or our competitors;
- · changes in our growth rate or our competitors' growth rates;
- · strategic actions by us or our competitors, such as acquisitions or restructurings;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;
- · loss of any of key management personnel;
- · disputes or other developments with respect to intellectual property rights;
- product liability claims or other litigation;
- public concern as to the safety or efficacy of our products;
- the public's reaction to our press releases and other public announcements and our filings with the SEC;
- sales of common stock by us, our significant stockholders, executive officers or directors;
- changes in stock market analyst recommendations or earnings estimates regarding our common stock, other comparable companies or our industry generally;
- changes in expectations or future performance;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business; and
- changes in health care policy in the United States and internationally, including changes in the availability of third-party reimbursement.

A significant decline in the price of our common stock could result in substantial losses for individual stockholders and could lead to costly and disruptive securities litigation.

#### We do not intend to pay dividends for the foreseeable future.

We have never declared or paid any dividends on our common stock and we currently intend to retain all of our earnings for the foreseeable future to finance the operation and expansion of our business, and do not anticipate paying any cash dividends in the future. As a result, our stockholders will only receive a return on their investment in our common stock if the market price of our common stock increases.

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

#### **ITEM 2. PROPERTIES**

Our corporate headquarters is located in Plymouth, Minnesota. Our peripheral vascular and cardiovascular businesses are also headquartered in Plymouth, Minnesota and include our primary sales, manufacturing, warehousing, research and development and administrative activities. We also have sales, manufacturing and research and development activities located in Redwood City, California and Menlo Park, California. The sales, manufacturing and research and development activities of our neurovascular business are primarily located in Irvine, California. Outside the United States, our European headquarters is in Paris, France, and includes our sales and marketing, and administrative activities. Our European warehouse facilities are located in Maastricht, Netherlands and London, England. In addition to our sales office in Paris, we have European sales and marketing offices in Bonn, London, Madrid, Maastricht, Milan and Stockholm.

Our corporate headquarters is located in a 50,000 square foot building in Plymouth, Minnesota, which is subject to a lease that extends to February 28, 2010. Our manufacturing, research and development functions operate from a 64,000 square foot facility in Plymouth, which is subject to a lease that extends to October 31, 2009. Our 60,000 square foot facility located at 740 Bay Road, Redwood City, California is subject to a lease that extends to September 2011 with an option to renew through 2016. We also lease a 46,000 square foot facility located at 900 Chesapeake Drive, Redwood City, California and a 12,000 square foot facility in Menlo Park, California. The lease for the 900 Chesapeake Bay facility is for 10 years commencing on November 3, 2006 with two options to extend the term each for an additional five-year period. The lease for the Menlo Park facility is a noncancelable operating lease commencing in January 2007 and extending through January 2012. We also occupy a 96,400 square foot facility in Irvine, California, which is subject to a lease that extends to April 30, 2011 and is subject to an option to extend the lease for an additional six years. Our distribution center in the United States is located in Brooklyn Park, Minnesota and occupies 16,000 square feet. Our European warehouse facility in Maastricht, Netherlands occupies 6,900 square feet and we also have a smaller warehouse facility in London, England.

We believe that our premises are adequate for our needs for the foreseeable future.

#### ITEM 3. LEGAL PROCEEDINGS

We are from time to time subject to, and are presently involved in, various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of our business. Our significant legal proceedings are discussed in Note 19 to our consolidated financial statements and incorporated herein by reference. While it is not possible to predict the outcome for most of the legal proceedings discussed in Note 19, the costs associated with such proceedings could have a material adverse effect on our consolidated results of operations, financial position or cash flows of a future period.

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted to a vote of our security holders during the fourth quarter ended December 31, 2007.

#### ITEM 4A. EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers, their ages and positions held, as of March 1, 2008, are as follows:

Name	Age	Position
James M. Corbett	49	Chairman, President and Chief Executive Officer
Stacy Enxing Seng	43	Senior Vice President and President, Peripheral Vascular and FoxHollow Technologies Divisions
Matthew Jenusaitis	46	Senior Vice President and President, Neurovascular Division
Pascal E.R. Girin	48	Senior Vice President and President, International
Kevin M. Klemz	46	Senior Vice President, Secretary and Chief Legal Officer
P. Richard Lunsford	50	Senior Vice President and President, U.S. Commercial Operations
Gregory Morrison	44	Senior Vice President, Human Resources
David H. Mowry	45	Senior Vice President, Corporate Manufacturing
Patrick D. Spangler	52	Senior Vice President and Chief Financial Officer
Julie D. Tracy	46	Senior Vice President and Chief Communications Officer

Each of our executive officers serves at the discretion of our board of directors and holds office until his or her successor is elected and qualified or until his or her earlier resignation or removal. Information regarding the business experience of our executive officers is set forth below.

James M. Corbett has served as our Chairman of the Board since August 2007 and our President and Chief Executive Officer since January 2004. Mr. Corbett was a member of the board of managers of ev3 LLC from August 2003 through the date of the merger of ev3 LLC with and into ev3 Inc. on June 21, 2005. From October 2003 to January 2004, Mr. Corbett served as the President and Chief Operating Officer of ev3 LLC. From January 2002 to October 2003, Mr. Corbett served as our Executive Vice President and President International. Mr. Corbett served as chairman of the board of directors of Micro Therapeutics, Inc. from January 2002 to January 2006 and as its Acting President and Chief Executive Officer from April 2002 through October 2002. From February 2001 to January 2002, Mr. Corbett worked as an independent medical device consultant. From January 1999 to February 2001, Mr. Corbett was President and Chief Executive Officer of Home Diagnostics, Inc., a medical device company. Prior to that, he served as Senior Vice President and then President for International of Boston Scientific Corporation, which followed his tenure as Vice President of International at SCIMED Life Systems, Inc. Mr. Corbett has a Bachelor of Science in Business Administration from the University of Kansas.

Stacy Enxing Seng has served as our President, FoxHollow Technologies Division since October 2007, Senior Vice President since August 2007 and President, Peripheral Vascular Division since March 2005. Ms. Enxing Seng previously served as our Vice President, Marketing and New Business Development. Ms. Enxing Seng has served in various positions since April 2001. From March 1999 to April 2001, she served as Vice President of Marketing for the cardiology division at Boston Scientific/SCIMED. Ms. Enxing Seng has a Bachelor of Arts in Public Policy from Michigan State University and a Master of Business Administration from Harvard University.

Matthew Jenusaitis has served as our Senior Vice President since August 2007 and President, Neurovascular Division since April 2006. Prior to joining ev3, Mr. Jenusaitis had been in the medical device industry for over 20 years, including positions at Baxter Healthcare Corporation, SCIMED Life Systems, Inc. and Boston Scientific Corporation. From July 2003 to August 2005, Mr. Jenusaitis served as President of Boston Scientific's Peripheral Interventions business. Mr. Jenusaitis has a Bachelor of Science in Chemical Engineering from Cornell University, a Master of Biochemical Engineering from Arizona State University and a Master of Business Administration from the University of California, Irvine.

Pascal E.R. Girin has served as our Senior Vice President since August 2007 and President, International since July 2005. Mr. Girin previously served as our General Manager, Europe from September 2003 to July 2005. From September 1998 to August 2003, Mr. Girin served in various capacities at BioScience Europe Baxter Healthcare Corporation, most recently as Vice President. Mr. Girin received an Engineering Education at the French Ecole des Mines.

Kevin M. Klemz has served as our Senior Vice President since August 2007 and Secretary and Chief Legal Officer since January 2007. Prior to joining ev3, Mr. Klemz was a partner in the law firm Oppenheimer Wolff & Donnelly LLP where he was a corporate lawyer for over 20 years. Mr. Klemz has a Bachelor of Arts in Business Administration from Hamline University and a Juris Doctorate from William Mitchell College of Law.

P. Richard Lunsford has served as our Senior Vice President and President, U.S. Commercial Operations since October 2007. Prior to joining ev3, Mr. Lunsford served as the Chief Executive Officer of Acorn Cardiovascular, Inc., a medical device company specializing in treatments for heart failure, from December 2001 to October 2007.

Gregory Morrison has served as our Senior Vice President, Human Resources since August 2007 and from March 2002 to August 2007 as our Vice President, Human Resources. From March 1999 to February 2002, Mr. Morrison served as Vice President of Organizational Effectiveness for. Thomson Legal & Regulatory, a division of The Thomson Corporation that provides integrated information solutions to legal, tax, accounting, intellectual property, compliance, business and government professionals. Mr. Morrison has a Bachelor of Arts in English and Communications from North Adams State College and a Master of Arts in Corporate Communications from Fairfield University.

David H. Mowry has served as our Senior Vice President, Corporate Manufacturing since October 2007. Prior to October 2007, Mr. Mowry served as Vice President of Operations for ev3 Neurovascular since November 2006. From February 2004 to November 2006, Mr. Mowry served as Vice President of Operations and Logistics at the ZimmerSpine division of Zimmer Holdings Inc., a reconstructive and spinal implants, trauma and related orthopaedic surgical products company. Prior to Zimmer, Mr. Mowry was the President and Chief Operating Officer of HeartStent Corp., a medical device company. Mr. Mowry is a graduate of the United States Military Academy in West Point, New York with a degree in Engineering and Mathematics.

Patrick D. Spangler has served as our Senior Vice President since August 2007 and our Chief Financial Officer since April 2005. From April 2005 to February 2008, Mr. Spangler also served as our Treasurer. From June 1997 to January 2005, Mr. Spangler served as the Executive Vice President, Chief Financial Officer and Assistant Secretary for Empi, Inc., a company specializing in rehabilitative medical devices. From January 2005 until March 2005, Mr. Spangler served as a consultant to Empi, Inc. Mr. Spangler has a Bachelor of Science in Accounting from the University of Minnesota, a Master of Business Administration from University of Chicago and a Master of Business Taxation from the University of Minnesota.

Julie D. Tracy has served as our Senior Vice President and Chief Communications Officer since January 2008. From March 2007 to November 2007, Ms. Tracy served as Vice President, Chief Communications Officer of Kyphon Inc., a medical device company that was purchased by Medtronic, Inc. in November 2007. From April 2005 to March 2007, Ms. Tracy served as Vice President, Investor Relations and Corporate Marketing of Kyphon Inc. From January 2003 to April 2005, Ms. Tracy served as Vice President of Marketing at Kyphon Inc. Prior to joining Kyphon Inc., Ms. Tracy held senior level positions in marketing, business development and reimbursement at Thoratec Corporation from January 1998 to January 2003. Ms. Tracy has a Bachelor of Science in Business Administration from the University of Southern California and a Master of Business Administration from Pepperdine University.

#### PART II

# ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### **Market Price**

Our common stock is listed for trading on The NASDAQ Global Select Market under the symbol "EVVV." Our common stock has traded on that market, which is formerly known as The NASDAQ National Market System, since the date of our initial public offering on June 16, 2005.

The following table sets forth, in dollars and cents (in lieu of fractions), the high and low daily sales prices for our common stock, as reported by The NASDAQ Global Select Market, for each fiscal quarter during 2007 and 2006.

u.	High	Low
2007		
First Quarter	\$21.34	\$17.03
Second Quarter	\$21.54	\$16.42
Third Quarter		\$15.06
Fourth Quarter	\$18.84	\$11.66
	High	Low
2006		Low
First Quarter	• .	<u>Low</u> \$13.83
First Quarter	\$17.98 \$18.00	
First Quarter	\$17.98 \$18.00	\$13.83

## Number of Record Holders; Dividends

As of March 1, 2008, there were 146 record holders of our common stock. To date, we have not declared or paid any cash dividends on our common stock. The restrictive covenants in our loan agreement with Silicon Valley Bank limit our ability to pay cash dividends.

### Recent Sales of Unregistered Equity Securities

During the fourth quarter ended December 31, 2007, we did not issue or sell any shares of our common stock or other equity securities of our company without registration under the Securities Act of 1933, as amended.

### **Issuer Purchases of Equity Securities**

The following table sets forth the information with respect to purchases made by or on behalf of us or any "affiliated purchaser" (as defined in Rule 10b-18(a)(3) under the Securities Exchange Act of 1934), of shares of our common stock during the fourth quarter ended December 31, 2007.

Period	Total Number of Shares Purchased(1)	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs(2)	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs(2)
Month # 1 (October 1, 2007 — October 31, 2007)	15,721	\$16.53	N/A	N/A
Month # 2 (November 1, 2007 — November 30, 2007)	6,600	15.40	N/A	N/A
Month # 3 (December 1, 2007 — December 31, 2007)	10,125	12.71	<u>N/A</u>	<u>N/A</u>
Total:	32,446	\$15.11	N/A	N/A

<sup>(1)</sup> Consists of shares repurchased from employees in connection with the required payment of withholding or employment-related tax obligations due in connection with the vesting of restricted stock awards.

Except as set forth in the table above, we did not purchase any shares of our common stock or other equity securities of our company registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended, during the fourth quarter ended December 31, 2007.

<sup>(2)</sup> Our board of directors has not authorized any repurchase plan or program for purchase of our shares of common stock or other equity securities on the open market or otherwise, other than an indefinite number of shares in connection with the cashless exercise of outstanding stock options and the surrender of shares of common stock upon the issuance or vesting of stock grants to satisfy any required withholding or employment-related tax obligations.

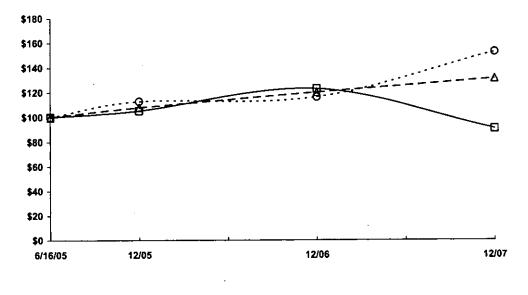
### Stock Performance Graph

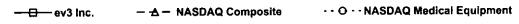
The following graph compares the annual cumulative total stockholder return on our common stock from June 16, 2005, the date of our initial public offering, until December 31, 2007, with the annual cumulative total return over the same period of The NASDAQ Stock Market (U.S.) Index and The NASDAQ Medical Equipment Index.

The comparison assumes the investment of \$100 in each of our common stock, The NASDAQ Stock Market (U.S.) Index and The NASDAQ Medical Equipment Index on June 16, 2005, and the reinvestment of all dividends.

## COMPARISON OF 30 MONTH CUMULATIVE TOTAL RETURN\*

Among ev3 Inc., The NASDAQ Composite Index And The NASDAQ Medical Equipment Index





\* \$100 invested on 6/16/05 in stock or on 5/31/05 in index-including reinvestment of dividends. Fiscal year ending December 31.

The foregoing Stock Performance Graph shall not be deemed to be "filed" with the Securities and Exchange Commission or subject to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended. Notwithstanding anything to the contrary set forth in any of our previous filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, that might incorporate future filings, including this annual report on Form 10-K, in whole or in part, the foregoing Stock Performance Graph shall not be incorporated by reference into any such filings.

### ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data set forth our results of operations and balance sheet data for the fiscal years and as of the dates indicated.

	For the Year Ended December 31,								
	2007(1)		2006		2005		2004	_	2003
	(dollars in thousands, except per unit and per share amounts)						•		
Results of Operations:									
Sales		·							
Product sales	\$ 278,226	\$	202,438	\$	133,696	\$	86,334	\$	67,639
Research collaboration	5,957					_			
Net sales	284,183		202,438		133,696		86,334		67,639
Operating expenses:									
Product cost of goods sold	99,879		71,321		55,094		39,862		30,218
Research collaboration:	1,065				_		_		_
Sales, general and administrative	195,267		141,779		130,427		103,031		82,479
Research and development	48,413		26,725		39,280		38,917		45,145
Amortization of intangible assets	20,306		17,223		10,673		9,863		12,078
(Gain) loss on sale of assets, net	(978)		162		200		(14,364)		14
Acquired in-process research and									
development	70,700		1,786		868				488
Special charges	19,054					_			
Total operating expenses	453,706		258,996		236,542		177,309		170,422
Loss from operations	(169,523)		(56,558)		(102,846)		(90,975)	(	102,783)
Other (income) expense:									
Loss (gain) on sale of investments,									
net	116		(1,063)		(4,611)		(1,728)		(3,409)
Interest (income) expense, net	(1,910)		(1,695)		9,916		25,428		12,673
Minority interest in loss of									
subsidiary	<del></del>				(2,013)		(13,846)		(3,808)
Other (income) expense, net	(2,934)		(2,117)		3,360		(1,752)		(1,606)
Loss before income taxes	(164,795)		(51,683)		(109,498)		(99,077)	(	106;633)
Income tax expense	949		688		526		196		303
Net loss	(165,744)		(52,371)		(110,024)		(99,273)	(	106,936)
Accretion of preferred membership units			,		•				
to redemption value(2)					12,061	_	23,826		7,651
Net loss attributable to common									
unit/share holders	<u>\$ (165,744)</u>	\$	(52,371)	\$_	(122,085)	\$	(123,099)	<u>\$(</u>	114,587)
Net loss per common unit/share(3):					<del>,</del>		<del></del>		<del></del> _
Basic and diluted	\$(2.37)	\$	(0.93)	\$	(4.48)	\$	(57.44)	\$	(130.67)
	<u> </u>	<u>-</u>		Ě		Ť		<u> </u>	<u> </u>
Weighted average units/shares outstanding:									
Basic and diluted	69 909 708	54	6 585 025	2	7,242,712	2	142 086	,	876,894
	07,707,708	=	0,505,025	=	1,474,114	=	, 172, 700	=	70,074

<sup>(1)</sup> We acquired FoxHollow Technologies, Inc. on October 4, 2007. The acquisition was accounted for under the purchase method of accounting and the results of operations of FoxHollow have been included in our consolidated results as of the acquisition date. In connection with the acquisition, we recorded

- \$14.9 million of integration costs associated with the acquisition and recognized \$70.7 million for in-process research and development charges. For a more complete description of these items and their impact on our consolidated financial results, see Note 4 to our consolidated financial statements.
- (2) The accretion of preferred membership units to redemption value presented above is based on the rights to which the Class A and Class B preferred membership unit holders of ev3 LLC were entitled related to a liquidation, dissolution or winding up of ev3 LLC. Notwithstanding this accretion right, in connection with the merger of ev3 LLC with and into ev3 Inc., each membership unit representing a preferred equity interest in ev3 LLC was converted into one share of our common stock and did not receive any additional rights with respect to the liquidation preference. Accretion was discontinued upon conversion of the preferred units to common equity at the time of our initial public offering on June 21, 2005.
- (3) Net loss per common unit/share and number of units/shares used in per unit/share calculations reflect our June 21, 2005 one for six reverse stock split for all periods presented.

	As of December 31,						
	2007	2006	2005	2004	2003		
		(do					
Balance Sheet Data:			• "				
Cash and cash equivalents	\$ 81,060	\$ 24,053	\$ 69,592	\$ 20,131	\$ 23,625		
Short-term investments	9,744	14,700	12,000				
Current assets	228,370	135,845	151,675	68,609	58,687		
Total assets	1,087,106	352,826	296,828	212,046	207,023		
Current liabilities excluding demand notes	119,159	41,767	37,671	36,025	32,379		
Demand notes payable-related parties		_		299,453	213,033		
Total liabilities	128,625	47,592	38,523	336,180	250,676		
Preferred membership units		_	_	254,028	230,202		
Total members' and stockholders' equity (deficit)	958,481	305,234	245,455	(394,472)	(285,672)		

# ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis provides material historical and prospective disclosures intended to enable investors and other users to assess our financial condition and results of operations. Statements that are not historical are forward-looking and involve risks and uncertainties discussed under the headings "Item 1. Business — Forward-Looking Statements" and "Item 1A. Risk Factors" of this report. The following discussion of our results of operations and financial condition should be read in conjunction with our consolidated financial statements and the related notes thereto included elsewhere in this report. This Management's Discussion and Analysis is organized in the following major sections:

- Business Overview. This section provides a brief overview description of our business, focusing in particular on developments during the most recent fiscal year.
- Summary of 2007 Results and 2008 Outlook. This section provides a brief summary of our financial results and financial condition for fiscal 2007 and our outlook for fiscal 2008.
- Sales and Expense Components. This section provides a description of the significant line items in our consolidated statement of operations.
- Results of Operations. This section provides our analysis of the significant line items in our consolidated statement of operations.
- Seasonal and Quarterly Fluctuations. This section describes the effects of seasonal and quarterly fluctuations in our business.

- Liquidity and Financial Resources. This section provides an analysis of our liquidity and cash flow and a discussion of our outstanding debt and commitments.
- Critical Accounting Policies and Estimates. This section discusses the accounting estimates that are considered important to our financial condition and results of operations and require us to exercise subjective or complex judgments in their application. All of our significant accounting policies, including our critical accounting estimates, are summarized in Note 2 to our consolidated financial statements.
- Recent Accounting Pronouncements. This section discusses recent accounting pronouncements that have had or may affect our results of operations and financial condition.

#### **Business Overview**

We are a leading global medical device company focused on catheter-based technologies for the endovascular treatment of vascular diseases and disorders. Within the endovascular market, we have targeted our business strategy efforts on the peripheral vascular and neurovascular markets, which we believe offer high growth potential with fewer entrenched competitors. We are focused on emerging and under-innovated opportunities which treat peripheral and neurovascular patients around the world, a strategy that we believe allows us to compete with smaller companies that have narrow product lines and lack an international sales force and infrastructure, yet also compete with larger companies that do not have our focus and agility.

We believe the overall market for endovascular devices will grow as the demand for minimally invasive treatment of vascular diseases and disorders continues to increase. We intend to capitalize on this market opportunity by the continued introduction of new products. We expect to originate these new products primarily through our internal research and development and clinical efforts, but we may supplement them with acquisitions or other external collaborations. Additionally, our growth has been, and will continue to be, impacted by our expansion into new geographic markets and the expansion of our direct sales organization in existing geographic markets.

In October 2007, we completed our acquisition of FoxHollow Technologies, Inc. FoxHollow designs, develops, manufactures and sells medical devices primarily for the treatment of peripheral artery disease and for the removal of thrombus. FoxHollow's principal product is the SilverHawk Plaque Excision System, which is a minimally invasive catheter system that treats peripheral artery disease by removing plaque in order to reopen narrowed or blocked arteries. The FoxHollow acquisition has created a combined company that we believe possesses one of the largest U.S. distribution footprints in peripheral and neurovascular devices with one of the broadest and most technologically advanced product offerings. Our product portfolio includes a broad spectrum of over 100 products consisting of over 1,000 SKUs to treat vascular disease in both the peripheral and neurovascular markets, including stents, atherectomy and thrombectomy products, PTA balloons, embolic protection devices, infusion catheters/wires, embolic coils and liquid embolics. As a result of our FoxHollow acquisition, we also are engaged in a research collaboration with Merck & Co., Inc. for the analysis of atherosclerotic plaque removed from patient arteries with the goal of identifying new biomarkers for atherosclerotic disease progression and new therapies for atherosclerotic disease.

Our management, including our chief executive officer who is our chief operating decision maker, report and manage our operations in two reportable business segments based on similarities in the products sold, customer base and distribution system. Our peripheral vascular segment, which was formerly referred to as our cardio peripheral segment, contains products that are used primarily in peripheral vascular procedures by radiologists, vascular surgeons and cardiologists and in targeted cardiovascular procedures. Our neurovascular segment contains products that are used primarily by neuroradiologists and neurosurgeons. Our sales activities and operations are aligned closely with our business segments. We generally have dedicated peripheral vascular sales teams in the United States and Europe that target customers who perform primarily peripheral vascular procedures and separate, dedicated neurovascular sales teams in the United States and Europe that are specifically focused on our neurovascular business customer base.

We have corporate infrastructure and direct sales capabilities in the United States, Canada, Europe and other countries and have established distribution relationships in the United States, Canada and selected international markets. Our corporate headquarters and our principal manufacturing, research and development, and U.S. sales operations for our peripheral vascular product line are located in Plymouth, Minnesota. Our FoxHollow atherectomy and thrombectomy products are manufactured in Redwood City, California. Our manufacturing, research and development, and U.S. sales operations for our neurovascular product lines are located in Irvine, California. Outside of the United States, our primary office is in Paris, France.

We sell our products in more than 60 countries and have dedicated substantial resources to building our U.S. and international direct sales and marketing infrastructure that includes a worldwide sales force of approximately 400 sales professionals as of December 31, 2007 in the United States, Canada and Europe. Our direct sales representatives accounted for approximately 87% of our net sales during 2007 and 2006, with the balance generated by independent distributors. In 2007, we were awarded three, three-year contracts by Novation, the health care contracting and services company of VHA and the University Health System Consortium, two national health care alliances, providing their nearly 2,500 hospital members and affiliates access to certain of our peripheral vascular and neurovascular products. In addition, in 2007, we were awarded a single-source, new technology agreement by Novation for our Onyx Liquid Embolic System. We expanded the sales force selling our neurovascular products in late 2007 from approximately 20 sales representatives to 25 sales representatives by December 31, 2007 primarily to support the launch of the Axium Detachable Coil System.

Since our acquisition of FoxHollow, we have spent considerable time and resources integrating our two operations, including in particular, our U.S. peripheral vascular sales force, and training our combined sales force on our combined product offering and cross-selling opportunities. We reduced the number of our U.S. peripheral vascular sales representatives from approximately 328 at the time of our acquisition of FoxHollow to approximately 210 as of December 31, 2007. We also have focused on our international strategy for SilverHawk. During fourth quarter 2007, we performed our first SilverHawk case in Europe and have focused on training physicians, establishing key opinion leaders, conducting European clinical research and developing specific product and procedure reimbursement strategies to support our international sales efforts for our FoxHollow products.

In order to drive sales growth, we have invested heavily throughout our history in not only the expansion of our global distribution system, but also new product development and clinical trials to obtain regulatory approvals. A significant portion of our net sales has historically been, and we expect to continue to be, attributable to new and enhanced products. In 2007, we launched our Protégé RX Carotid Stents, additional lengths in our EverFlex family of stents and our SilverHawk LS-M and MS-M products in the United States for the peripheral vascular market and our Axium coil for the neurovascular market. To date, in 2008, we have launched the SilverHawk LX-M device in the United States and received FDA clearance for our RockHawk Atherectomy System for surgical use. Our focus in 2007 and continuing in 2008 is to further validate the clinical and competitive benefits of our technology platforms to drive new and enhanced products. To accomplish this, we have a number of clinical trials underway and others that are currently in development, including our DURABILITY I trial in Europe measuring the durability of our Protégé EverFlex stent in SFA lesions, our DURABILITY II trial in the United States with the objective of expanding our EverFlex stent's U.S. indication to include treatment of peripheral artery disease, our PROVE-IT trial designed to study the use of balloon-expandable and self-expanding stents for percutaneous stent treatment in iliac vessels and our U.S. clinical trial for percutaneous removal of calcium using our RockHawk and SpiderFX devices.

#### Summary of 2007 Results and Outlook for 2008

While the financial results of our first three fiscal quarters of 2007 were characterized by strong net sales growth in both our peripheral vascular and neurovascular business segments as well as domestic and international markets, our fourth fiscal quarter of 2007 results were substantially and adversely affected by the completion of our acquisition of FoxHollow and difficulties in integrating the combined businesses. Our U.S. peripheral vascular business in particular was negatively impacted by greater than anticipated sales force integration challenges related to the FoxHollow acquisition and higher than expected customer inventory levels

of SilverHawk products. Although we believe that certain actions we have taken, including eliminating a layer of sales management and optimizing the size of our U.S. peripheral vascular sales organization, will enable us to overcome the integration challenges and support our future growth objectives, no assurance can be provided that such actions will do so and we still expect such challenges and factors to continue to adversely affect our net sales into the second half of 2008.

We remain confident in the strategic and financial rationale for our FoxHollow acquisition. One of the key benefits of the acquisition was the opportunity to combine two experienced sales forces with well-established physician relationships and to leverage the combined company's expanded product portfolio to increase sales through cross-selling opportunities. While our cross-selling initiative did not gain the traction we had expected during fourth quarter 2007, we have reduced the combined company's expense base and anticipate realizing approximately \$70 million in expense savings on an annual basis going forward as a result of the acquisition and believe we now have the appropriate sales structure and focus in place to take advantage of the potential revenue synergies.

In 2008, we intend to focus on expanding our position in the peripheral vascular market by offering a full complement of innovative products through our large direct sales organization, taking advantage of cross-selling opportunities and leveraging our recent agreements with Novation to gain access to new customers, continuing our expansion in international markets, investing in development of next generation products, such as the RockHawk, and supporting the necessary clinical trial initiatives to drive broader product and procedure adoption and to bring new products to market. While our outlook for 2008 remains positive, we will continue to keep a cautionary eye on continuing difficulties integrating our FoxHollow business, customer inventory levels, decreased demand for our SilverHawk products, regulatory actions, developments in outstanding and threatened litigation, competitive actions and other factors identified under the heading "Item 1A. Risk Factors" contained elsewhere in this report, which could cause our actual results to differ from our anticipated outlook.

Our fiscal 2007 results and financial condition included the following items of significance, some of which we expect may also affect our results and financial condition in 2008:

- Our net sales increased 40% to \$284.2 million in 2007 compared to 2006 reflecting sales growth in
  each of our reportable business segments and geographic markets. In particular, our sales growth was
  positively affected by an increase in sales of our EverFlex self-expanding stents and neurovascular
  products, increased market penetration of products introduced during the past two years and our
  acquisition of FoxHollow.
- Net sales of our peripheral vascular products increased 43% to \$173.8 million in 2007 compared to 2006 primarily as a result of increased market penetration of our EverFlex and Protégé RX Carotid Stents, SpiderFX Embolic Protection Device and PTA balloon catheters and our acquisition of FoxHollow, partially offset by sales declines in older generation products. We expect our peripheral vascular sales to increase in 2008 as compared to 2007 primarily as a result of increased cross-selling opportunities as a result of our acquisition of FoxHollow, the introduction of our atherectomy products into international markets, additional market penetration of products launched during 2006 and 2007 and new product introductions anticipated in 2008. We believe that our atherectomy, stent and embolic protection sales will continue to contribute to our sales growth in our peripheral vascular segment in 2008 as compared to 2007.
- Net sales of our neurovascular products increased 28% to \$104.4 million in 2007 compared to 2006 primarily as a result of increased market penetration of our existing products, including in particular our Onyx Liquid Embolic System for the treatment of brain arterial-venous malformations and our Axium coil, which was launched on a worldwide basis in fourth quarter 2007, and sales growth in virtually all of our neurovascular access and delivery products, partially offset by sales declines in older generation products. We expect our neurovascular sales to increase in 2008 as compared to 2007 due to market growth, developing new customer accounts, additional market penetration of products launched during 2007 and 2006, and new product introductions anticipated in 2008, including our Solitaire Flow Restoration stent which we have recently started to selectively commercialize in Europe.

- In October 2007, we completed our acquisition of FoxHollow, which broadened our peripheral vascular product offering to include atherectomy and additional thrombectomy products, including in particular the SilverHawk Plaque Excision System. Our net sales in 2007 included \$20.9 million of net sales from FoxHollow products.
- As a result of our FoxHollow acquisition, we now recognize research collaboration revenue and incur research collaboration expense from our collaboration and license agreement with Merck. Research collaboration revenue, which is recognized on a straight-line basis over the four-year term of the license/exclusivity portion of the agreement and further limited to cumulative amounts due and collected at any given point under the arrangement, was \$6.0 million in 2007. Research collaboration expense was \$1.1 million in 2007. As a result of Dr. Simpson's resignation from our board of directors in February 2008, Merck has the right to terminate the collaboration and license agreement at any time within six months of Dr. Simpson's resignation. We expect that research collaboration expense will fluctuate in absolute dollars and as a percentage of our research collaboration revenue as the amount of services we perform under the agreement will vary from period to period.
- Approximately 38% of our net sales during 2007 were generated outside of the United States compared to 40% during 2006. The sales growth in our international markets was primarily a result of new product introductions and increased market penetration of existing products. Changes in foreign currency exchange rates had a positive impact of \$6.0 million on our 2007 net sales as compared to a positive impact of \$443,000 on our 2006 net sales, principally resulting in both periods from the performance of the Euro against the U.S. dollar.
- In our peripheral vascular segment, product cost of goods sold as a percentage of product sales decreased to 30% in 2007 compared to 43% in 2006 primarily attributable to increased sales volumes, offset by the commencement of royalty payments in 2007 on certain of our nitinol products, the write-up of FoxHollow inventory as required under purchase accounting which increased product cost of goods sold by \$1.8 million when the inventory was sold in the fourth quarter 2007, and adjustments in our excess and obsolete inventory reserves for the planned discontinuance of the Primus balloon expandable stent and the Sailor .035 balloon due to our strategic marketing focus on new product introductions. In our neurovascular segment, cost of goods sold as a percentage of product sales decreased to 21% in 2007 compared to 24% in 2006 primarily attributable to increased sales volumes and on-going cost savings programs, offset by the commencement of royalty payments in 2007 on certain of our nitinol products. We expect product cost of goods sold as a percentage of product sales to decline in 2008 as compared to 2007 due to higher volumes in our manufacturing facilities and efficiency improvements from manufacturing initiatives, offset in part by anticipated conversion costs associated with new product launches anticipated to occur in 2008.
- We incurred special charges of \$19.1 million in 2007 as a result of us entering into agreements in
  principle to settle certain patent infringement and other litigation with The Regents of the University of
  California and Boston Scientific Corporation in the third quarter. We have not yet entered into final
  definitive settlement agreements but expect to do so in the near future.
- Our operating expenses increased 75% in 2007 compared to 2006 primarily as a result of our acquisition of FoxHollow. In 2007, our operating expenses included a charge of \$70.7 million for acquired in-process research and development as a result of the acquisition. We expect our sales, general and administrative expenses, research and development expense and amortization of intangible assets to increase in absolute dollars in 2008 as compared to 2007. We expect sales, general and administrative expenses and research and development to decline as a percentage of net sales.
- In April 2007, we completed a secondary public offering issuing 2,500,000 shares of our common stock which generated approximately \$44.5 million in net proceeds to us.
- At the time of the FoxHollow acquisition, FoxHollow had \$166.9 million in cash, cash equivalents and short-term investments. We used \$99.3 million to pay FoxHollow stockholders the cash portion of the

- merger consideration. Total consideration for the transaction was \$856.9 million and is discussed further in Note 4 of the consolidated financial statements included elsewhere in this report.
- Our subsidiaries, ev3 Endovascular, Inc., ev3 International, Inc., Micro Therapeutics, Inc. and FoxHollow Technologies, Inc., are parties to a loan and security agreement with Silicon Valley Bank, consisting of a \$30 million revolving line of credit and a \$12.5 million equipment financing line. In March 2007, we increased the four-year equipment financing line from \$7.5 million to \$12.5 million. The revolving line of credit expires in June 2008.
- Our net loss for 2007 increased to \$165.7 million, or \$2.37 per share, in 2007 compared to \$52.4 million, or \$0.93 per share, in 2006. Our focus for 2008 is to improve our profitability. Although we expect to generate cash from operations in 2008, no assurance can be provided that we will do so, especially if we incur significant unanticipated costs or do not achieve our anticipated net sales during 2008.
- Our cash, cash equivalents and short-term investments available to fund our current operations were \$90.8 million at December 31, 2007. We believe our cash, cash equivalents, short-term investments, anticipated cash from operations and current and anticipated financing arrangements will be sufficient to meet our liquidity requirements through at least the next 12 months.

### Sales and Expense Components

The following is a description of the primary components of our net sales and expenses:

Product net sales. We derive our product net sales from the sale of endovascular devices in two primary business segments: peripheral vascular and neurovascular devices. Most of our sales are generated by our global, direct sales force and are shipped and billed to hospitals or clinics throughout the world. In countries where we do not have a direct sales force, sales are generated by shipments to distributors who, in turn, sell to hospitals and clinics. In cases where our products are held in consignment at a customer's location, we generate sales at the time the product is used in surgery and we are notified in writing by the hospital that the product was used, rather than at shipment. We charge our customers for shipping and record shipping income as part of net sales.

Research collaboration (revenue). Research collaboration revenue is derived from our collaboration and license agreement with Merck, which we assumed as a result of our acquisition of FoxHollow. Under the agreement, Merck agreed to pay FoxHollow \$40 million in equal installments over the initial four-year term of the research collaboration, in exchange for FoxHollow's agreement to collaborate exclusively with Merck during such period with respect to certain fields. Merck may extend these exclusivity obligations, on a year-to-year basis, in the event it also elects to extend the term of the collaboration beyond the initial four-year term, by making additional payments to us of \$10 million per year, which Merck may offset against its royalty and milestone obligations during such year. Under the agreement, Merck also agreed to provide a minimum of \$60.0 million in funding to FoxHollow over the first three years of the four-year collaboration program term, for research activities to be conducted by FoxHollow under Merck's direction. In the event Merck extends the collaboration beyond its initial four-year term, Merck would be required to fund our additional activities under the collaboration on an as-performed basis. We will receive milestone payments on successful development of drug products or diagnostic tests utilizing results from the collaboration, as well as royalties on sales by Merck of drugs and diagnostic products developed through the collaboration. Our research collaboration revenue from Merck is recognized on a straight-line basis over the four-year term of the license/exclusivity portion of the agreement and further limited to cumulative amounts due and collected at any given point under the arrangement. For additional discussion, see Note 2 to our consolidated financial statements included elsewhere in this report. As a result of Dr. Simpson's resignation from our board of directors in February 2008, Merck has the right to terminate the collaboration and license agreement. Merck may exercise this right at any time within six months of Dr. Simpson's resignation.

Product cost of goods sold. We manufacture a substantial majority of the products that we sell. Our product cost of goods sold consists primarily of direct labor, allocated manufacturing overhead, raw materials,

components and royalties and excludes amortization of intangible assets, which is presented as a separate of component of operating expenses.

Research collaboration (expense). Research collaboration expense consists primarily of costs associated with procurement and delivery of tissue samples and costs of research activities conducted by us under our collaboration and license agreement with Merck. We expect that research collaboration expense will fluctuate in absolute dollars and as a percentage of our research collaboration revenue as the amount of services we perform under the agreement varies from period to period.

Sales, general and administrative expenses. Our selling and marketing expenses consist primarily of sales commissions and support costs for our global, direct distribution system, marketing costs and freight expense that we pay to ship products to customers. General and administrative expenses consist primarily of salaries and benefits, compliance systems, accounting, finance, legal, information technology, human resources and facility costs.

Research and development. Research and development expense includes costs associated with the design, development, testing, deployment, enhancement and regulatory approval of our products. It also includes costs associated with the design and execution of our clinical trials and regulatory submissions.

Amortization of intangible assets. Intangible assets, such as purchased completed technology, distribution channels and intellectual property, including trademarks and patents, are amortized over their estimated useful lives. Intangible assets are amortized over periods ranging from 2.5 to 10 years.

(Gain) loss on sale of assets, net. (Gain) loss on sale of assets, net includes the difference between the proceeds received from the sale of an operating asset and its carrying value.

Acquired in-process research and development. Acquired in-process research and development is related to value assigned to those projects acquired in business combinations or in the acquisition of assets for which the related products have not received regulatory approval and have no alternative future use.

Special charges. Special charges relate to recent agreements in principle to settle certain patent infringement and other litigation between us, The Regents of the University of California and Boston Scientific Corporation. Products involved in the litigation include embolic protection devices and certain detachable embolic coils. The special charges include amounts to be paid by us to the parties and legal fees and expenses associated with the litigation. For additional discussion, see Note 19 to our consolidated financial statements included elsewhere in this report.

(Gain) loss on sale of investments, net. (Gain) loss on sale of investments, net includes the difference between the proceeds received from the sale of an investment and its carrying value. In addition, this caption includes losses from other than temporary declines in investments accounted for on a cost basis.

Interest (income) expense, net. Interest (income) expense, net consists primarily of interest expense associated with loans from Silicon Valley Bank and, prior to our initial public offering in 2005, from our principal investors, Warburg Pincus and The Vertical Group. Interest income results from interest earned on investments in investment-grade, interest-bearing securities and money market accounts.

Minority interest in loss of subsidiary. Minority interest in loss of subsidiary is the portion of Micro Therapeutics, Inc.'s net losses allocated to minority stockholders in 2005.

Other (income) expense, net. Other (income) expense, net primarily includes foreign currency exchange (gains) losses net of certain other expenses.

Income tax expense. Income tax expense is generated in certain of our European subsidiaries. Due to our history of operating losses, we have not recorded tax benefits for U.S. income taxes through 2007.

Accretion of preferred membership units to redemption value. Accretion of preferred membership units to redemption value represents the increase in carrying value of preferred membership units of ev3 LLC prior to ev3 LLC's merger with and into us in June 2005. The increase in carrying value was based on the rights to which the preferred membership units were entitled related to a liquidation, dissolution or winding up of

ev3 LLC. Accretion was recorded as a reduction to members' equity and increased the loss attributable to common unit holders. Accretion was discontinued upon conversion of the preferred units to common equity at the time of our initial public offering in June 2005.

# **Results of Operations**

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts (in thousands), and the changes between the specified periods expressed as percent increases or decreases:

•		the Year Ended ecember 31,	l 	For		
Results of Operations:	2007	2006	Percent Change	2006	2005	Percent Change
Sales						
Product sales	\$ 278,226	\$202,438	37.4%	\$202,438	\$ 133,696	51.4%
Research collaboration	5,957		NM			NM
Net sales	284,183	202,438	40.4%	202,438	133,696	51.4%
Operating expenses:	•					
Product cost of goods sold	99,879	71,321	40.0%	71,321	55,094	29.5%
Research collaboration	1,065	_	NM	-	_	NM
Sales, general and administrative	195,267	141,779	37.7%	141,779	130,427	8.7%
Research and development	48,413	26,725	81.2%	26,725	39,280	(32.0)%
Amortization of intangible assets	20,306	17,223	17.9%	17,223	10,673	61.4%
(Gain) loss on sale of assets, net	(978)	162	NM	162	200	NM
Acquired in-process research and	,					
development	70,700	1,786	NM	1,786	868	NM
Special charges	19,054	=	NM			NM
Total operating expenses	453,706	258,996	75.2%	258,996	236,542	9.5%
Loss from operations	(169,523)	(56,558)	NM	(56,558)	(102,846)	(45.0)%
Other (income) expense:						
Loss (gain) on sale of investments,						
net	116	(1,063)	NM	(1,063)	(4,611)	(76.9)%
Interest (income) expense, net	(1,910)	(1,695)	· NM	(1,695)	9,916	NM
Minority interest in loss of	, , ,	,		( , ,	,	
subsidiary	_		NM		(2,013)	NM
Other (income) expense, net	(2,934)	(2,117)	NM	(2,117)	3,360	NM
Loss before income taxes	(164,795)	(51,683)	NM	(51,683)	(109,498)	(52.8)%
Income tax expense	949	688	37.9%	688	526	30.8%
Net loss	(165,744)	(52,371)	NM	(52,371)	(110,024)	(52.4)%
Accretion of preferred membership		• • •		, , ,	,	, ,
units to redemption value(1)		=	NM		12,061	NM
Net loss attributable to common				<del></del> _		
share/unit holders	<u>\$(165,744</u> )	<u>\$(52,371</u> )	NM	\$(52,371)	<u>\$(122,085)</u>	(57.1)%

<sup>(1)</sup> The accretion of preferred membership units to redemption value presented above is based on the rights to which the Class A and Class B preferred membership unit holders of ev3 LLC were entitled related to a liquidation, dissolution or winding up of ev3 LLC. Notwithstanding this accretion right, in connection with the merger of ev3 LLC with and into us, each membership unit representing a preferred equity interest in ev3 LLC was converted into the right to receive one share of our common stock and did not receive any additional rights with respect to the liquidation preference. Accretion was discontinued upon conversion of the preferred units to common equity at the time of our initial public offering in June 2005.

The following tables set forth, for the periods indicated, our net sales by segment and geography expressed as dollar amounts (in thousands) and the changes in net sales between the specified periods expressed as percentages:

	For the Yo Decem		Percent	For the Year Ended December 31,		Percent		
Net Sales by Segment	2007	2006	Change	2006	2005	Change		
Peripheral vascular:			•					
Atherectomy	\$ 20,884	\$ <del></del>	100.0%	\$ <u> </u>	\$ <del>-</del>			
Stents	86,035	64,092	34.2%	64,092	37,871	69.2%		
Thrombectomy and embolic protection	25,998	21,606	20.3%	21,606	12,869	67.9%		
Procedural support and other	40,858	35,406	15.4%	35,406	<u>29,141</u>	21.5%		
Total Peripheral vascular	\$173,775	\$121,104	43.5%	\$121,104	\$ 79,881	51.6%		
Neurovascular:								
Embolic products	\$ 56,003	\$ 38,998	43.6%	\$ 38,998	\$ 22,463	73.6%		
Neuro access and delivery products	48,448	42,336	14.4%	42,336	31,352	35.3%		
Total Neurovascular	\$104,451	\$ 81,334	28.4%	\$ 81,334	·\$ 53,815	51.1%		
Research collaboration:	\$ 5,957	<u> </u>	100.0%	<u>\$</u>	<u>\$</u>	_		
Total net sales	<u>\$284,183</u>	<u>\$202,438</u>	40.4%	<u>\$202,438</u>	<u>\$133,696</u>	51.4%		
	For the Year Ended December 31,				Percent	For the Year Ended December 31,		Percent
Net Sales by Geography	2007	2006	Change	2006	2005 .	Change		
United States	\$177,198	\$121,180	46.2%	\$121,180	\$ 71,848	68.7%		
International								
Before foreign exchange impact	101,020	81,258	24.3%	80,815	61,848	30.7%		
Foreign exchange impact	5,965		_	443		<u> </u>		
Total	106,985	81,258	31.7%	81,258	61,848	31.4%		
Total	<u>\$284,183</u>	<u>\$202,438</u>	40.4%	<u>\$202,438</u>	<u>\$133,696</u>	51.4%		

# Comparison of the Year Ended December 31, 2007 to the Year Ended December 31, 2006

Net sales. Net sales increased 40% to \$284.2 million in 2007 compared to \$202.4 million in 2006, reflecting sales growth in each of our reportable business segments and geographic markets. In particular, our sales growth was positively affected by an increase in sales of our EverFlex self-expanding stents and neurovascular products, increased market penetration of products introduced during the past two years and our acquisition of FoxHollow. Our net sales in 2007 included \$20.9 million of net sales from FoxHollow products and \$6.0 million from research collaboration activities during fourth quarter 2007.

Net sales of peripheral vascular products. Net sales of our peripheral vascular products increased 43% to \$173.8 million in 2007 compared to \$121.1 million in 2006, primarily due to increased market penetration of our EverFlex family of stents and sales of atherectomy products as a result of our acquisition of FoxHollow. Net sales in our atherectomy product line, which consisted primarily of sales of our SilverHawk Plaque Excision System, were \$20.9 million in 2007. Net sales in our stent product line increased 34% to \$86.0 million in 2007 compared to \$64.1 million in 2006. This growth is attributable to increased market penetration of our EverFlex and Protégé RX Carotid Stents, partially offset by sales declines in older generation products. Net sales of our thrombectomy and embolic protection devices increased 20% to \$26.0 million in 2007 compared to \$21.6 million largely due to increased market penetration of our SpiderFX Embolic Protection Device, partially offset by sales declines in older generation products. Net sales of our

procedural support and other products increased 15% to \$40.9 million in 2007 compared to \$35.4 million in 2006 largely due to increased market penetration of our PTA balloon catheters in the United States.

Net sales of neurovascular products. Net sales of our neurovascular products increased 28% to \$104.4 million in 2007 compared to \$81.3 million in 2006, primarily as a result of increased penetration of existing products and sales growth in virtually all of our neurovascular access and delivery products. Sales of our embolic products increased 44% to \$56.0 million in 2007 compared to \$39.0 million in 2006 primarily due to increased market penetration of our Onyx Liquid Embolic System for the treatment of brain AVMs and our Axium coil. Sales of our neuro access and delivery products increased 14% to \$48.4 million in 2007 compared to \$42.3 million in 2006 largely as a result of volume increases across virtually all neurovascular product lines.

Research collaboration (revenue). Research collaboration revenue is derived from our collaboration and license agreement with Merck, which we assumed as a result of our acquisition of FoxHollow. Our research collaboration revenue from Merck is recognized on a straight-line basis over the four-year term of the license/exclusivity portion of the agreement and further limited to cumulative amounts due and collected at any given point under the arrangement. For additional discussion, see Note 2 to our consolidated financial statements included elsewhere in this report. Revenue from our research collaboration was \$6.0 million in 2007.

Net sales by geography. Net sales in the United States increased 46% to \$177.2 million in 2007 compared to \$121.2 million in 2006. International net sales increased 32% to \$107.0 million in 2007 compared to \$81.2 million in 2006 and represented 38% of total net sales in 2007 compared to 40% in 2006. International net sales include a favorable foreign currency exchange rate impact of approximately \$6.0 million compared to a favorable impact of \$443,000 in 2006, principally resulting in both periods from the performance of the Euro against the U.S. dollar. Our direct sales force operations in Europe produced net sales of \$65.7 million in 2007, which represented 68.1% of our total international net sales growth in 2007 as compared to 2006, with the remainder coming from our distribution operations in the Asia Pacific, Canada, Latin America and Middle East markets. The sales growth in our international markets was primarily a result of new product introductions and increased market penetration of existing products.

Product cost of goods sold. As a percentage of product net sales, product cost of goods sold represented 36% of our product sales in 2007 compared to 35% in 2006. In our peripheral vascular segment, product cost of goods sold as a percentage of product sales decreased to 30% in 2007 compared to 43% in 2006 primarily attributable to increased sales volumes, offset by the commencement of royalty payments in 2007 on certain of our nitinol products, the write-up of FoxHollow inventory as required under purchase accounting which increased product cost of goods sold by \$1.8 million when the inventory was sold in the fourth quarter 2007, and adjustments in our excess and obsolete inventory reserves for the planned discontinuance of the Primus balloon expandable stent and the Sailor .035 balloon due to our strategic marketing focus on new product introductions. In our neurovascular segment, cost of goods sold as a percentage of product sales decreased to 21% in 2007 compared to 24% in 2006 primarily attributable to increased sales volumes and on-going cost savings programs, offset by the commencement of royalty payments in 2007 on certain of our nitinol products.

Research collaboration (expense). Research collaboration expense consists primarily of costs associated with procurement and delivery of tissue samples and costs of research activities conducted by us under our collaboration and license agreement with Merck. Research collaboration expense incurred was \$1.1 million for the 2007.

Sales, general and administrative expenses. Sales, general and administrative expenses increased 38% to \$195.3 million in 2007 compared to \$141.8 million in 2006. The increase was primarily due to additional staffing resulting in higher personnel costs of \$21.7 million, \$14.9 million of integration costs related to our acquisition of FoxHollow, \$6.7 million of additional costs as a result of additional staffing and overall activity related to FoxHollow, an unfavorable impact of foreign currency exchange rates on international operating expenses of \$4.3 million and \$3.0 million increase in non-cash stock-based compensation costs.

Research and development expense. As a percentage of net sales, research and development expense increased to 17% in 2007 compared to 13% in 2006. This increase was due primarily to increased spending on clinical trials and the additional activity related to our acquisition of FoxHollow in 2007.

Amortization of intangible assets. Amortization of intangible assets increased 18% to \$20.3 million in 2007 compared to \$17.2 million in 2006. The increase was primarily the result of the amortization of intangible assets purchased in connection with our acquisition of FoxHollow and the amortization of our Invatec distribution rights which we received in February 2007, slightly offset by certain intangible assets becoming fully amortized in 2007. For additional discussion of the amortization of intangible assets purchased in connection with our acquisition of FoxHollow, see Note 4 to our consolidated financial statements included elsewhere in this report.

Acquired in-process research and development. During the fourth quarter of 2007, we recorded \$70.7 million in acquired in-process research and development projects that had not yet reached technological feasibility and had no future alternative use in connection with the FoxHollow acquisition. At the time we acquired FoxHollow, we expected all acquired in-process research and development to reach technological feasibility; however there is no assurance that these projects will attain commercial viability. The endovascular device market is highly competitive and designs change often to adjust to patent constraints and to changing market preferences. Therefore, product life cycles are relatively short. If we do not introduce new products and technologies, or if our new products and technologies are not accepted by the physicians who use them or the payors who reimburse the costs of the procedures performed with them, or if there are any delays in our introduction of new products, we may not be successful in attaining commercial viability for these projects.

We may experience delays in any phase of a product launch, including during research and development, clinical trials, regulatory approvals, manufacturing, marketing and the education process. Many of our clinical trials have durations of several years and it is possible that competing therapies, such as drug therapies, may be introduced while our products are still undergoing clinical trials. New products and technologies introduced by competitors may reach the market earlier, may be more effective or less expensive than our products or render our products obsolete.

The most significant acquired research and development projects were the Next Generation SilverHawk project and RockHawk project which represents 92% of the acquired research and development projects. We attributed approximately \$51.2 million of fair value to the Next Generation SilverHawk project. The SilverHawk Plaque Excision System is a minimally invasive catheter system that treats peripheral artery disease by removing plaque in order to reopen narrowed or blocked arteries. The Next Generation SilverHawk is designed to improve the procedure time, cutting efficiency and ease of use in the existing SilverHawk system. We expect to incur approximately \$7.3 million to bring the Next Generation SilverHawk device to commercial viability. We estimate that we will realize cash flows from the Next Generation SilverHawk device during the first half of 2009.

We attributed approximately \$13.7 million of fair value to the RockHawk project. The RockHawk is designed to treat calcified lesions with a stronger blade. We expect to incur approximately \$3.4 million to bring the RockHawk device to commercial viability. In February 2008, we received approval for surgical use of the RockHawk device in the United States. We are currently working with the FDA on a clinical trial design and Investigational Device Exemption submission for peripheral use. The realization of cash flows related to the RockHawk device is contingent on the timing of the FDA approval for peripheral use. For further discussion, see Note 4 to our consolidated financial statements included elsewhere in this report.

Special charges. Special charges of \$19.1 million were recorded in third quarter 2007 as a result of us entering into agreements in principle to settle certain patent infringement and other litigation with The Regents of the University of California and Boston Scientific Corporation. The \$19.1 million special charge consists of amounts expected to be paid by us to the parties and our legal fees and expenses associated with the litigation. For additional discussion, see Note 19 to our consolidated financial statements included elsewhere in this report.

(Gain) loss on sale of investments, net. (Gain) loss on sale of investments, net was a loss of \$116,000 in 2007 compared to a gain of \$1.1 million in 2006. In 2006, we received a final \$910,000 milestone payment related to the 2002 sale of our investment in Enteric Medical Technologies, Inc. and a \$153,000 milestone payment related to the 2005 sale of Genyx Medical, Inc.

Interest (income) expense, net. Interest (income) expense, net was comprised of the following (in thousands):

	2007	2006
Interest income	\$(3,284)	\$(2,469)
Interest expense	1,374	<u>774</u>
Interest (income) expense, net	<u>\$(1,910)</u>	<u>\$(1,695)</u>

Net interest income was \$1.9 million in 2007 compared to \$1.7 million in 2006. This increase was attributable to increased interest earned on higher average cash and short-term investment balances primarily a result of cash acquired in our acquisition of FoxHollow and net proceeds received from our secondary public offering, partially offset by increased levels of interest charges incurred on our outstanding borrowings under our equipment financing. See Note 12 to the consolidated financial statements included elsewhere in this report.

Other (income) expense, net. Other (income) expense, net was income of \$2.9 million in 2007 compared to income of \$2.1 million in 2006. The other (income) expense, net in 2007 and 2006 was primarily due to foreign currency exchange rate gains (losses).

Income tax expense. We incurred modest levels of income tax expense in 2007 and 2006 related to certain of our European sales offices. We recorded no provision for U.S. income taxes in 2007 or in 2006 due to our history of operating losses.

#### Comparison of the Year Ended December 31, 2006 to the Year Ended December 31, 2005

Net sales. Net sales increased 51% to \$202.4 million in 2006 compared to \$133.7 million in 2005, primarily as a result of new product introductions and the market penetration of products introduced in 2006 and 2005.

Net sales of peripheral vascular products. Net sales of our peripheral vascular products increased 52% to \$121.1 million in 2006 compared to \$79.9 million in 2005. Key new product launches that contributed to the sales increase for 2006 included our Protégé EverFlex stents and SpideRX embolic protection device, both of which were approved by the U.S. FDA during the first quarter 2006. This sales growth was also driven by increased market penetration of our Protégé family of self-expanding stents and sales of our PTA balloon catheters in the United States. Net sales in our stent product line increased 69% to \$64.1 million in 2006 compared to \$37.9 million in 2005. This increase is attributable to increased market penetration of our EverFlex, Protégé GPS, Primus and ParaMount Mini families of stents, partially offset by sales declines in older generation products. Net sales of our thrombectomy and embolic protection devices increased 68% to \$21.6 million in 2006 largely due to the introduction of the SpideRX in the U.S. and continued market penetration internationally, partially offset by sales declines in older generation products. Net sales of our procedural support and other products increased 21% to \$35.4 million in 2006 compared to 2005, largely due to increased market penetration of our PTA balloon catheters in the United States.

Net sales of neurovascular products. Net sales of our neurovascular products increased 51% to \$81.3 million in 2006 compared to \$53.8 million in 2005, primarily as a result of increased market penetration of our Onyx Liquid Embolic System and Nexus coils, as well as continued penetration of our microcatheters and occlusion balloon systems. Sales of our embolic products increased 74% to \$39.0 million in 2006 compared to 2005 primarily due to increased market penetration of our Onyx Liquid Embolic System for the treatment of brain AVMs since its United States launch in July 2005, volume increases in such product internationally and volume increases in our Nexus family of embolic coils. Sales of our neuro access and delivery products increased 35% to \$42.3 million in 2006 compared to 2005 largely as a result of volume

increases across multiple product lines, including the Echelon microcatheters and the HyperForm and HyperGlide occlusion balloon systems.

Net sales by geography. Net sales in the United States increased 69% to \$121.2 million in 2006 compared to \$71.8 million in 2005. International net sales increased 31% to \$81.2 million in 2006 compared to \$61.8 million in 2005 and represented 40% of our total net sales in 2006 compared to 46% in 2005. International net sales include a favorable foreign currency exchange rate impact of approximately \$443,000 compared to 2005, principally resulting from the performance of the Euro against the U.S. dollar. Our direct sales force operations in Europe produced net sales of \$48 million in 2006, which represented 61% of the total international net sales growth in 2006 as compared to 2005, with the remainder coming from our distribution operations in the Asia Pacific, Canada, Latin America and Middle East markets. The sales growth in our international markets was primarily a result of new product introductions and increased product penetration.

Product cost of goods sold. As a percentage of product sales, product cost of goods sold decreased to 35% of product sales in 2006 compared to 41% in 2005. This decrease was primarily attributable to our continued growth in sales volumes, ongoing investments in in-house manufacturing capabilities and cost savings achieved related to facility consolidation and our implementation and use of lean manufacturing concepts. In our peripheral vascular segment, product cost of goods sold as a percentage of product sales decreased to 43% in 2006 compared to 48% in 2005 primarily attributable to on-going investments in in-house manufacturing capabilities, facility consolidation and increased sales volumes. In our neurovascular segment, product cost of goods sold as a percentage of product sales decreased to 24% in 2006 compared to 31% in 2005 due in part to the consolidation of our neurovascular manufacturing operations into our Irvine, California facility during the second quarter 2005. Our increased production volumes and on-going cost savings programs also contributed to the decrease.

Sales, general and administrative expenses. Sales, general and administrative expenses increased 9% to \$141.8 million in 2006 compared to \$130.4 million in 2005. The increase was due to a \$2.7 million increase in non-cash stock-based compensation costs, increased international distribution costs of \$1.1 million related to rent and freight costs, increases in general staffing levels and higher selling expenses related to the expansion of our neurovascular sales force. New product introductions also contributed to the increase. Although these expenses increased in absolute dollars, as a percentage of net sales, sales, general and administrative expenses decreased to 70% in 2006 compared to 98% of net sales in 2005.

Research and development expense. As a percentage of net sales, research and development expense decreased to 13% in 2006 compared to 29% in 2005. This reduction was due to the increase in net sales combined with a decrease in clinical study expenses related to the completion of certain clinical trials in 2005. The decrease in clinical costs was partially offset by increased spending on certain internal development efforts.

Amortization of intangible assets. Amortization of intangible assets increased 61% to \$17.2 million in 2006 compared to \$10.7 million in 2005. This increase was primarily a result of additional amortizable intangible assets recorded as part of our acquisition of the remaining outstanding shares of MTI in January 2006.

Acquired in-process research and development. During 2006, we incurred a charge of \$1.8 million for acquired in-process research and development as a result of our acquisition of the outstanding shares of MTI that we did not already own. During 2005, we incurred a charge of \$868,000 for acquired in-process research and development as a result of The Vertical Group's contribution to ev3 LLC of shares of MTI. This contribution was accounted for under the purchase method of accounting based upon the proportionate ownership contributed to ev3 LLC. For additional discussion of this amount, see Note 4 to our consolidated financial statements included elsewhere in this report.

(Gain) loss on sale of investments, net. (Gain) loss on sale of investments, net was a gain of \$1.1 million in 2006 compared to a gain of \$4.6 million in 2005. In 2006, we received a final \$910,000 milestone payment related to the 2002 sale of our investment in Enteric Medical Technologies, Inc. and a \$153,000 milestone payment related to the 2005 sale of Genyx Medical, Inc. In 2005, we received a \$3.7 million milestone

payment related to the sale of our investment in Genyx Medical, Inc. and received a \$878,000 milestone payment related to our 2002 sale of our investment in Enteric Medical Technologies, Inc.

Interest (income) expense, net. Interest (income) expense, net was comprised of the following (in thousands):

	2006	2005
Interest income	\$(2,469)	\$ (2,475)
Interest expense	<u>774</u>	_12,391
Interest (income) expense, net	<u>\$(1,695</u> )	\$ 9,916

Net interest income was \$1.7 million in 2006 compared to net interest expense of \$9.9 million in 2005. A portion of the net proceeds from our initial public offering in June 2005 were invested in short-term, investment grade, interest-bearing securities contributing interest income of \$2.5 million during the full year 2006. We also used a portion of the net proceeds to reduce our financing balance to zero resulting in a reduction of interest expense in 2006 as compared to 2005.

Other (income) expense, net. Other (income) expense, net was income of \$2.1 million in 2006 compared to expense of \$3.4 million in 2005. This change was primarily related to improvements in foreign currency exchange rate gains (losses) in 2006 as compared to 2005.

Income tax expense. We incurred modest levels of income tax expense in 2006 and 2005 related to certain of our European sales offices. We recorded no provision for U.S. income taxes in 2006 or in 2005 due to our history of operating losses.

Accretion of preferred membership units to redemption value. Accretion of preferred membership units to redemption value was recorded up to the date of our initial public offering in June 2005, at which time all preferred units were converted into common shares.

# Seasonality and Quarterly Fluctuations

Our business is seasonal in nature. Historically, demand for our products has been the highest in our fourth fiscal quarter. We traditionally experience lower sales volumes in our third fiscal quarter than throughout the rest of the year as a result of the European holiday schedule during the summer months.

We have experienced and expect to continue to experience meaningful variability in our net sales and gross profit among quarters, as well as within each quarter, as a result of a number of factors, including, among other things, the timing and extent of promotional pricing or volume discounts; the timing of larger orders by customers and the timing of shipment of such orders; changes in average selling prices; the number and mix of products sold in the quarter; the availability and cost of components and materials; costs, benefits and timing of new product introductions; and the timing and amount of services performed under our license and collaboration agreement with Merck.

# Liquidity and Capital Resources

The following table highlights several items from our consolidated balance sheet:

	As of December 31,		
Balance Sheet Data		2006	
	(Dollars in t	thousands)	
Cash and cash equivalents	\$ 81,060	\$ 24,053	
Short-term investments	9,744	14,700	
Total current assets	228,370	135,845	
Total assets	1,087,106	352,826	
Total current liabilities	119,159	41,767	
Total liabilities	128,625	47,592	
Total stockholders' equity	958,481	305,234	

# Working Capital

Financing history. We have generated significant operating losses since our inception. These operating losses, including cumulative non-cash charges for acquired in-process research and development of \$199.4 million, have resulted in an accumulated deficit of \$781.0 million as of December 31, 2007. We have historically financed our operations with private investments by our principal stockholders and public equity offerings.

In June 2005, we completed an initial public offering of our common stock in which we sold 11,970,800 shares of our common stock at \$14.00 per share, resulting in net proceeds to us of approximately \$154.9 million, after deducting underwriting discounts and commissions and offering expenses. In April 2007, we completed a secondary public offering of our common stock in which we sold 2,500,000 shares of our common stock at \$19.00 per share, resulting in net proceeds to us of approximately \$44.5 million. In October 2007, we completed our acquisition of FoxHollow. At the time of the acquisition, FoxHollow had \$166.9 million in cash, cash equivalents and short-term investments. We used \$99.3 million to pay FoxHollow stockholders the cash portion of the merger consideration. For additional discussion, see Note 4 to our consolidated financial statements included elsewhere in this report.

Credit facility. Our subsidiaries, ev3 Endovascular, Inc., ev3 International, Inc., Micro Therapeutics, Inc. and FoxHollow Technologies, Inc., which we collectively refer to as the "borrowers", are parties to a loan and security agreement, which we refer to as the loan agreement, with Silicon Valley Bank, or SVB, consisting of a \$30.0 million revolving line of credit and up to \$12.5 million of equipment financing advances which consist of (i) a \$7.5 million equipment advance made available to the borrowers on June 28, 2006 ("Equipment Advance A") and (ii) a \$5 million equipment advance made available to the borrowers on March 15, 2007 ("Equipment Advance B"). After repayment, no equipment advance may be reborrowed. The revolving line of credit expires in June 2008 and, Equipment Advance A matures in June 2010 while Equipment Advance B matures on the last day of March 2011.

Pursuant to the terms of the loan agreement and subject to specified reserves, we may borrow under the revolving line of credit up to \$12.0 million without any borrowing base limitations. Aggregate borrowings under the revolving line of credit that exceed \$12.0 million will subject the revolving line to borrowing base limitations. These limitations allow us to borrow, subject to specified reserves, up to 80% of eligible domestic and foreign accounts receivables plus up to 30% of eligible inventory. Additionally, borrowings against the eligible inventory may not exceed the lesser of 33% of the amount advanced against accounts receivable or \$7.5 million. Borrowings under the revolving line bear interest at a variable rate per annum equal to SVB's prime rate. Borrowings under the equipment advances bear interest at a variable rate per annum equal to SVB's prime rate plus 1.0%. The prime rate at December 31, 2007 was 7.25%. Accrued interest on any outstanding balance under the revolving line and the equipment financing advances is payable monthly in arrears. Amounts that were outstanding under the Equipment Advance A as of December 31, 2006 are payable in 42 consecutive equal monthly installments of principal, beginning on January 31, 2007. Amounts that were outstanding under the Equipment Advance B are payable in 42 equal monthly payments of principal,

commencing on the last day of the seventh month following the date that the Equipment Advance B was made and continuing on the last day of each month thereafter until the last day of the 48th month following the date of such advance. As of December 31, 2007, we had \$5.4 million in outstanding borrowings under the Equipment Advance A and \$4.6 million in outstanding borrowings under the Equipment Advance B and no outstanding borrowings under the revolving line of credit; however, we had approximately \$2.4 million of outstanding letters of credit issued by SVB, which reduces the maximum amount available under our revolving line of credit to approximately \$27.6 million.

Both the revolving line of credit and equipment financing are secured by a first priority security interest in substantially all of our assets, excluding intellectual property, which is subject to a negative pledge, and are guaranteed by us and all of our domestic direct and indirect subsidiaries. The loan agreement requires the borrowers to maintain a specified liquidity ratio. The loan agreement imposes certain limitations on the borrowers, their subsidiaries and us, including without limitation, limitations on their ability to: (i) transfer all or any part of their business or properties; (ii) permit or suffer a change in control; (iii) merge or consolidate, or acquire any entity; (iv) engage in any material new line of business; (v) incur additional indebtedness or liens with respect to any of their properties; (vi) pay dividends or make any other distribution on or purchase of, any of their capital stock; (vii) make investments in other companies; or (viii) engage in related party transactions, subject in each case to certain exceptions and limitations. The loan agreement requires us to maintain on deposit or invested with SVB or its affiliates the lesser of \$15.0 million or 50% of our aggregate cash and cash equivalents. The borrowers are required to pay customary fees with respect to the facility, including a fee on the average unused portion of the revolving line.

The toan agreement contains customary events of default, including the failure to make required payments, the failure to comply with certain covenants or other agreements, the occurrence of a material adverse change, failure to pay certain other indebtedness and certain events of bankruptcy or insolvency. Upon the occurrence and during the continuation of an event of default, amounts due under the loan agreement may be accelerated. We were in compliance with covenants at December 31, 2007 and expect to be in compliance for the foreseeable future.

Cash, cash equivalents and short-term investments. Our cash, cash equivalents and short-term investments available to fund our current operations were \$90.8 million and \$38.8 million at December 31, 2007 and 2006, respectively. We expect to generate cash from operations in 2008, although no assurance can be provided that we will do so, especially if we incur significant unanticipated costs or do not achieve our anticipated net sales during 2008. We believe our cash, cash equivalents, short-term investments, anticipated cash from operations and current and anticipated financing arrangements will be sufficient to meet our liquidity requirements through at least the next 12 months.

#### Cash Flows

Operating activities. Net cash used in operations was \$49.2 million in 2007 compared to \$46.9 million in 2006, reflecting primarily our net loss and increased working capital requirements during both periods. In 2007, our net loss included approximately \$110.6 million of non-cash charges for depreciation and amortization, acquired in-process research and development and stock-based compensation expense. In 2006, our net loss included approximately \$31.8 million of non-cash charges for depreciation and amortization, acquired in-process research and development and stock-based compensation expense. In 2005, our net loss included approximately \$20.6 million of non-cash charges for depreciation and amortization, acquired in-process research and development and stock-based compensation expense.

Investing activities. Net cash provided by investing activities was \$51.9 million in 2007 compared to net cash used in investing activities of \$16.0 million in 2006. During 2007, we acquired \$166.9 million in cash as a result of our acquisition of FoxHollow and used \$99.3 million of it to pay the cash portion of the merger consideration to FoxHollow's stockholders. During 2007, we also purchased \$13.8 million of property and equipment, \$3.3 million of patents and licenses and \$6.5 million of distribution rights related to our agreement with Invatec. During 2007, we received \$6.9 million in proceeds from the sale of short-term investments and \$2.0 million from the sale of assets. During 2006, we purchased property and equipment totaling \$12.0 million,

patents and licenses totaling \$3.5 million and short-term investments totaling \$6.8 million. These cash payments were partially offset by proceeds from short-term investments and proceeds from the sale of investments in 2006. During 2005, we purchased property and equipment totaling \$13.2 million and short-term investments totaling \$12.0 million. We also made a milestone payment related to a previous acquisition in the amount of \$3.7 million and \$1.9 million in merger related costs. These cash payments in 2005 were partially offset by the receipt of \$3.7 million from the sales of certain assets by Genyx Medical, Inc., in which Micro Therapeutics, Inc. held a minority interest, the receipt of a \$878,000 milestone payment related to the 2002 sales of an investment in Enteric Medical Technologies, Inc. and the receipt of \$2.1 million related the return of acquisition consideration resulting from a settlement of an acquisition dispute. Historically, our capital expenditures have consisted of purchases of manufacturing equipment, research and testing equipment, computer systems and office furniture and equipment. We expect to continue to make investments in property and equipment and to incur approximately \$20.0 million in capital expenditures during 2008.

Financing activities. Net cash provided by financing activities was \$54.0 million in 2007 compared to \$16.9 million in 2006. During 2006, we received proceeds from the issuance of our common stock in our secondary public offering, stock option exercises and borrowings under our increased equipment term loan with Silicon Valley Bank. During 2006, we received proceeds from stock option exercises and borrowings under our equipment term loan with Silicon Valley Bank. During 2005, cash provided by financing activities was \$206.7 million and consisted of \$154.9 million of net proceeds received from our initial public offering of our common stock and proceeds of \$49.1 million from the issuance of demand notes.

# Contractual Cash Obligations

At December 31, 2007, we had contractual cash obligations and commercial commitments as follows (in thousands):

	Payments Due by Period					
	Total_	Less than 1 Year	1-3 Years (Dollars in t	3-5 Years thousand)	More than 5 Years	Other
Notes payable	\$10,000	\$ 3,571	\$ 6,071	\$ 358	<b>\$</b> —	\$ —
Purchase commitments(1)	14,943	14,943	_	_	<del>-</del> .	
Operating leases(2)	26,595	6,456	9,727	3,909	6,503	_
FASB Interpretation 48 income tax obligations, including interest and penalties(3)	1,006	397				609
Total	\$52,544	\$25,367	<u>\$15,798</u>	<u>\$4,267</u>	<u>\$6,503</u>	<u>\$609</u>

<sup>(1)</sup> Represents commitments for minimum inventory purchases related to our distribution agreement with Invatec. We do not have any other significant purchase obligations for the delivery of goods or services or other commercial commitments. These payments are denominated in Euros and were translated in the tables above based on the respective U.S. dollar exchange rate at December 31, 2007. See Note 19 to our consolidated financial statements included elsewhere in this report.

<sup>(2)</sup> The amounts reflected in the table above for operating leases represent future minimum lease payments under non-cancelable operating leases primarily for certain office space, warehouse space, computers and vehicles. Portions of these payments are denominated in foreign currencies and were translated in the tables above based on their respective U.S. dollar exchange rates at December 31, 2007. These future payments are subject to foreign currency exchange rate risk. In accordance with U.S. generally accepted accounting principles, or GAAP, our operating leases are not recognized on our consolidated balance sheet.

<sup>(3)</sup> The FASB Interpretation 48 income tax obligations of \$609,000 included in the "other" column in the table above represent an amount of potential tax liabilities that we are uncertain as to if or when such amounts may be settled.

# Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by the rules and regulations of the SEC, that have or are reasonably likely to have a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these arrangements.

### Other Liquidity Information

The acquisition agreements relating to our purchase of Appriva Medical, Inc. and Dendron GmbH require us to make additional payments to the sellers of these businesses if certain milestones related to regulatory steps in the product commercialization process are achieved. The potential milestone payments total \$175.0 million and \$15.0 million with respect to the Appriva and Dendron acquisitions, respectively, during the period of 2003 to 2009. We have determined that the first milestone with respect to the Appriva agreement was not achieved by the January 1, 2005 milestone date and that the first milestone is not payable. In September 2005, we announced that we had decided to discontinue the development and commercialization of the technology we acquired in the Appriva transaction. We are currently involved in litigation regarding this agreement as described in more detail in Note 19 to our consolidated financial statements included elsewhere in this report. Under the terms of the stock purchase agreement entered into in connection with our acquisition of Dendron, we were required to make additional payments which are contingent upon Dendron products achieving certain revenue targets between 2003 and 2008. In 2003, the \$4.0 million revenue target for sales of Dendron products during 2003 was met. Accordingly, an additional payment to the former Dendron stockholders of \$3.75 million was made in 2004. In 2004, the \$5.0 million revenue target for sales of Dendron products during 2004 was met. Accordingly, a payment to the former Dendron stockholders of \$3.75 million was accrued in 2004 and was paid in 2005. A final payment of \$7.5 million was earned in 2007 as Dendron products achieved annual revenues of \$25.0 million. Accordingly, a payment to the former Dendron stockholders of \$7.5 million was accrued in 2007 and will be paid in second quarter 2008.

Pursuant to the acquisition agreement relating to FoxHollow's purchase of Kerberos Proximal Solutions, Inc., FoxHollow has agreed to pay certain earnout payments which are capped at \$117.0 million upon the achievement of contractually defined net sales milestones. In August 2007, FoxHollow received a letter from counsel for the shareholder representatives of Kerberos alleging that FoxHollow has not used commercially reasonable efforts to market, promote, sell and distribute Kerberos' Rinspirator products, as required under the agreement and plan of merger between FoxHollow and Kerberos. We have been in discussions with the shareholder representatives of Kerberos regarding their allegation. There can be no assurance that the stockholder representatives of Kerberos will not commence litigation on the alleged claims.

In June 2007, we sold and licensed, on a royalty-free perpetual basis, certain intellectual property relating to percutaneously delivered implants within the left atrial appendage for prevention of emboli migration out of the appendage. In connection with the sale, we also obtained a royalty-free perpetual license from the purchaser that allows us to use certain of the intellectual property sold to the purchaser outside of the left atrial appendage market. In exchange for the assets and the license, we received \$2.0 million in cash, shares of common stock of the purchaser representing approximately 8% of its equity on a fully diluted basis and an unsecured, subordinated, non-interest-bearing promissory note in the principal amount of \$5.6 million, the unpaid principal balance of which will become immediately due and payable only upon an initial public. offering by the purchaser or a sale transaction, in each case resulting in gross proceeds of less than a certain amount.

In October 2007, we paid \$856.9 million to acquire FoxHollow using a combination of our common stock, cash and fully and partially vested stock options and awards. In this transaction, we received cash, cash equivalents and short-term investments of \$166.9 million and paid cash of \$99.3 million. For additional discussion, see Note' 4 to our consolidated financial statements included elsewhere in this report.

Our future liquidity and capital requirements will be influenced by numerous factors, including the extent and duration of future operating losses, the level and timing of future sales and expenditures, the results and

scope of ongoing research and product development programs, working capital to support our sales growth, receipt of and time required to obtain regulatory clearances and approvals, sales and marketing programs, continuing acceptance of our products in the marketplace, competing technologies, market and regulatory developments, acquisitions and the future course of intellectual property and other litigation. We believe that our cash, cash equivalents, short-term investments, anticipated cash from operations and current and anticipated financing arrangements will be sufficient to meet our liquidity requirements through at least the next 12 months. In the event that we require additional working capital to fund future operations and any future acquisitions, we may sell shares of our common stock or other equity securities, sell debt securities, or enter into additional credit and financing arrangements with one or more independent institutional lenders. There is no assurance that any financing transaction will be available on terms acceptable to us, or at all, or that any financing transaction will not be dilutive to our current stockholders. If we require additional working capital, but are not able to raise additional funds, we may be required to significantly curtail or cease ongoing operations. From time to time, we may also sell a given technology or intellectual property having a development timeline or development cost that is inconsistent with our investment horizon or which does not adequately complement our existing product portfolio. See Note 3 and Note 19 to our consolidated financial statements included elsewhere in this report.

## **Critical Accounting Policies and Estimates**

Our consolidated financial statements and related financial information are based on the application of U.S. GAAP. Our most significant accounting policies are described in Note 2 to our consolidated financial statements included elsewhere in this report. The preparation of our consolidated financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes.

Certain of our more critical accounting policies require the application of significant judgment by management in selecting the appropriate assumptions for calculating financial estimates. By their nature, these judgments are subject to an inherent degree of uncertainty. These judgments are based on our historical experience, terms of existing contracts, our observance of trends in the industry, information provided by our physician customers and information available from other outside sources, as appropriate. Changes in accounting estimates are reasonably likely to occur from period to period. Changes in these estimates and changes in our business could have a material impact on the presentation of our financial condition, changes in financial condition or results of operations.

We believe that the following financial estimates are both important to the portrayal of our financial condition and results of operations and require subjective or complex judgments. Further, we believe that the items discussed below are properly recorded in our consolidated financial statements for all periods presented. Management has discussed the development, selection and disclosure of our critical financial estimates with the audit committee and our board of directors. The judgments about those financial estimates are based on information available as of the date of our consolidated financial statements. Our critical financial estimates are described below:

#### Revenue Recognition

We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104, Revenue Recognition, which requires that four basic criteria must be met before sales can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the price is fixed or determinable and (4) collectibility is reasonably assured. These criteria are met at the time of shipment when risk of loss and title passes to the customer or distributor, unless a consignment arrangement exists. Sales from consignment arrangements are recognized upon written notification that the product has been used by the customer indicating that a sale is complete. Our terms of sale for regular sales are typically FOB shipping point, net 30 days. Regular sales include orders from customers for replacement of customer stock, replenishment of consignment product used by customers, orders for a scheduled case/surgery and stocking orders.

We allow customers to return defective or damaged products for credit. Our estimate for sales returns is based upon contractual commitments and historical return experience which we analyze by geography and is recorded as a reduction of sales for the period in which the related sales occurred. Historically, our return experience has been low with return rates of less than 3.0% of our net sales.

# Stock-Based Compensation

We currently use the Black-Scholes option pricing model to determine the fair value of stock options and other equity incentive awards. The determination of the fair value of stock-based compensation awards on the date of grant using an option-pricing model is affected by our stock price, as well as assumptions regarding a number of complex and subjective variables which include the expected life of the award, the expected stock price volatility over the expected life of the awards, expected dividend yield, risk-free interest rate and the forfeiture rate.

We estimate the expected term of options based upon our historical experience. We estimate expected volatility and forfeiture rates based on a combination of historical factors related to our common stock since our June 2005 initial public offering and the volatility rates of a set of guideline companies. The guideline companies consist of public and recently public medical technology companies. The risk-free interest rate is determined using U.S. Treasury rates appropriate for the expected term. Dividend yield is estimated to be zero as we have never paid dividends and have no plans of doing so in the future.

We estimate forfeitures at the time of grant and revise those estimates in subsequent periods as necessary. We use historical data to estimate forfeitures and record stock-based compensation expense only for those awards that are expected to vest. Generally, all stock-based compensation is amortized on a straight-line basis over the respective requisite service periods, which are generally the vesting periods.

If factors change and we employ different assumptions for estimating stock-based compensation expense in future periods, the future periods may differ significantly from what we have recorded in the current period and could materially affect our results of operations. It may also result in a lack of comparability with other companies that use different models, methods and assumptions.

See Note 2 and Note 16 to our consolidated financial statements for further information regarding our SFAS 123(R) disclosures.

#### Allowance for Doubtful Accounts

We make judgments as to our ability to collect outstanding receivables and provide allowance for a portion of receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding account balances and the overall quality and age of those balances not specifically reviewed. In determining the provision for invoices not specifically reviewed, we analyze historical collection experience and current economic trends. If the historical data used to calculate the allowance provided for doubtful accounts does not reflect our future ability to collect outstanding receivables or if the financial condition of customers were to deteriorate, resulting in impairment of their ability to make payments, an increase in the provision for doubtful accounts may be required. We maintain a large customer base that mitigates the risk of concentration with one customer. However, approximately 19% of our outstanding receivables are from foreign distributors, which carry a potentially higher degree of risk. If the overall condition of the health care industry were to deteriorate, resulting in an impairment of our customers' ability to make payments, significant additional allowances could be required.

Our accounts receivable balance was \$66.2 million and \$45.1 million, net of accounts receivable allowances, comprised of both allowances for doubtful accounts and sales returns, of \$6.8 million and \$3.9 million at December 31, 2007 and 2006, respectively.

#### Excess and Obsolete Inventory

We calculate an inventory reserve for estimated obsolescence or excess inventory based on historical turnover and assumptions about future demand for our products and market conditions which includes

estimates of the impact of the introduction of new or enhanced products on existing inventory. Our industry is characterized by regular new product development, and as such, our inventory is at risk of obsolescence following the introduction and development of new or enhanced products. Our estimate and assumptions for excess and obsolete inventory are reviewed and updated on a quarterly basis. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our sales forecasts. Future product introductions and related inventories may require additional reserves based upon changes in market demand or introduction of competing technologies. Increases in the reserve for excess and obsolete inventory result in a corresponding expense to cost of goods sold. Our reserve for excess and obsolete inventory was \$11.0 million and \$4.7 million at December 31, 2007 and 2006, respectively. In the fourth quarter of 2007, our excess and obsolete inventory reserves, included approximately \$3.3 million of adjustments for the planned discontinuance of the Primus balloon expandable stent and the Sailor .035 balloon due to our strategic marketing focus on new product introductions.

# Valuation of Acquired In-Process Research and Development, Goodwill and Other Intangible Assets

When we acquire another company, the purchase price is allocated, as applicable, between acquired inprocess research and development, other identifiable intangible assets, tangible net assets and goodwill as
required by U.S. GAAP. In-process research and development is defined as the value assigned to those projects
for which the related products have not received regulatory approval and have no alternative future use.

Determining the portion of the purchase price allocated to in-process research and development and other
intangible assets requires us to make significant estimates that may change over time. During 2007, we
recorded an in-process research and development charge of \$70.7 million related to the October 4, 2007
acquisition of FoxHollow. During 2006, we recorded an in-process research and development charge of
\$1.8 million related to the January 6, 2006 acquisition of the remaining minority interest in MTI. For further
discussion see Note 4 of the consolidated financial statements included elsewhere in this report.

The income approach was used to determine the fair values of the acquired in-process research and development. This approach establishes fair value by estimating the after-tax cash flows attributable to the inprocess project over its useful life and then discounting these after-tax cash flows back to the present value. Revenue estimates were based on relative market size, expected market growth rates and market share penetration. Gross margin estimates were based on the estimated cost of the product at the time of introduction and historical gross margins for similar products offered by us or by competitors in the marketplace. The estimated selling, general and administrative expenses were based on historical operating expenses of the acquired company as well as long-term expense levels based on industry comparables. The costs to complete each project were based on estimated direct project expenses as well as the remaining labor hours and related overhead costs. In arriving at the value of acquired in-process research and development projects, we considered each project's stage of completion, the complexity of the work to be completed, the costs already incurred, the remaining costs to complete the project, the contribution of core technologies, the expected introduction date and the estimated useful life of the technology. The discount rate used to arrive at the present value of acquired in-process research and development as of the acquisition date was based on the time value of money and medical technology investment risk factors. We believe that the estimated acquired in-process research and development amounts determined represent the fair value at the date of acquisition and do not exceed the amount a third party would pay for the projects.

Goodwill represents the excess of the aggregate purchase price over the fair value of net assets, including in-process research and development, of the acquired businesses. Goodwill is tested for impairment annually, or more frequently if changes in circumstance or the occurrence of events suggest an impairment exists. We have not recorded impairment of goodwill in any of the years included in our consolidated statements of operations. Our estimates associated with the goodwill impairment tests are considered critical due to the amount of goodwill recorded on our consolidated balance sheets and the judgment required in determining fair value amounts, including projected future cash flows. Goodwill was \$586.6 million and \$149.1 million at December 31, 2007 and 2006, respectively.

Other intangible assets consist primarily of purchased developed technology, patents, customer relationships and trademarks and are amortized over their estimated useful lives, ranging from 2.5 to 10 years. We

review these intangible assets for impairment annually during our fourth fiscal quarter or as changes in circumstance or the occurrence of events suggest the remaining value may not be recoverable. We have not recorded an impairment of other intangible assets in any of the years included in our consolidated statements of operations. Other intangible assets, net of accumulated amortization, were \$231.0 million and \$40.0 million at December 31, 2007 and 2006, respectively.

The evaluation of asset impairments related to goodwill and other intangible assets, among other things, requires us to make assumptions about future cash flows over the life of the assets being evaluated. These assumptions require significant judgment and actual results may differ from assumed or estimated amounts.

# Accounting for Income Taxes

As part of the process of preparing our consolidated financial statements, we are required to determine our income taxes in each of the jurisdictions in which we operate. This process involves estimating our actual current tax expense together with assessing temporary differences resulting from recognition of items for income tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included on our consolidated balance sheets. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must reflect this increase as an expense within the tax provision in our consolidated statement of operations.

Management's judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We will continue to monitor the realizability of our deferred tax assets and adjust the valuation allowance accordingly. We have recorded a full valuation allowance on our net deferred tax assets of \$199.0 million and \$192.0 million as of December 31, 2007 and 2006, respectively. A portion of the valuation allowance will be recorded as a reduction to goodwill if and when that portion of the deferred tax asset is realized and the related valuation allowance is reversed.

On January 1, 2007, we adopted FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" (FIN 48). FIN 48 clarifies when tax benefits should be recorded in financial statements, requires certain disclosures of uncertain tax matters and indicates how any tax reserves should be classified in a balance sheet. As a result of this standard, we recorded a charge of \$717,000 which was accounted for as an increase in the January 1, 2007 balance of accumulated deficit.

#### **Recent Accounting Pronouncements**

In December 2007, the FASB issued SFAS No. 141 (Revised 2007) "Business Combinations" and SFAS No. 160 "Non-controlling Interests in Consolidated Financial Statements," which are effective for fiscal years beginning after December 15, 2008. These new standards represent the completion of the FASB's first major joint project with the International Accounting Standards Board (IASB) and are intended to improve, simplify, and converge internationally the accounting for business combinations and the reporting of noncontrolling interests (formerly minority interests) in consolidated financial statements. ev3 will adopt these standards at the beginning of its 2009 fiscal year. The effect of adoption will generally be prospectively applied to transactions completed after the end of the Company's 2008 fiscal year, although the new presentation and disclosure requirements for pre-existing non-controlling interests will be retrospectively applied to all prior-period financial information presented.

SFAS No. 141(R) retains the underlying fair value concepts of its predecessor (SFAS No. 141), but changes the method for applying the acquisition method in a number of significant respects including the requirement to expense transaction fees and expected restructuring costs as incurred, rather than including these amounts in the allocated purchase price; the requirement to recognize the fair value of contingent consideration at the acquisition date, rather than the expected amount when the contingency is resolved; the requirement to recognize the fair value of acquired in-process research and development assets at the acquisition date, rather than immediately expensing; and the requirement to recognize a gain in relation to a

bargain purchase price, rather than reducing the allocated basis of long-lived assets. Because this standard is generally applied prospectively, the effect of adoption on the Company's financial statements will depend primarily on specific transactions, if any, completed after 2008.

In September 2006, the FASB issued SFAS 157, "Fair Value Measurement." The standard provides guidance for using fair value to measure assets and liabilities. SFAS 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements would be separately disclosed by level within the fair value hierarchy. The statement is effective for us beginning in 2008. In February 2008, the FASB issued FASB Staff Position (FSP) SFAS No. 157-2, "Effective Date of FASB Statement No. 157" (FSP SFAS No. 157-2) that deferred the effective date of SFAS No. 157 for one year for certain nonfinancial assets and nonfinancial liabilities. We do not believe that the implementation of SFAS 157 will have a material impact on our results of operations and financial condition.

On February 15, 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115" (SFAS No. 159). SFAS No. 159 creates a "fair value option" under which an entity may elect to record certain financial assets or liabilities at fair value upon their initial recognition. Subsequent changes in fair value would be recognized in earnings as those changes occur. The election of the fair value option would be made on a contract-by-contract basis and would need to be supported by concurrent documentation or a preexisting documented policy. SFAS No. 159 requires an entity to separately disclose the fair value of these items on the balance sheet or in the footnotes to the financial statements and to provide information that would allow the financial statement user to understand the impact on earnings from changes in the fair value. SFAS No. 159 is effective for us beginning in 2008. We do not believe that the implementation of SFAS 159 will have a material impact on our results of operations and financial condition.

In December 2007, the FASB issued SFAS 160, "Noncontrolling Interests in Consolidated Financial Statements." SFAS 160 establishes new standards that will govern the accounting for and reporting of noncontrolling interests in partially owned subsidiaries. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008 and requires retroactive adoption of the presentation and disclosure requirements for existing minority interests. All other requirements shall be applied prospectively. As of December 31, 2007, we do not have any partially owned consolidated subsidiaries and therefore, we do not expect an impact related to the adoption of this accounting standard.

In June 2006, the FASB issued Emerging Issues Task Force Issue No. 06-3, "How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement (That Is, Gross versus Net Presentation)" (EITF 06-3). EITF 06-3 indicates that the presentation of taxes within the scope of this issue on either a gross or net basis is an accounting policy decision that should be disclosed. Our policy is to present the taxes collected from customers and remitted to governmental authorities on a net basis and are not material to our results of operations and financial condition.

In June 2007, the FASB issued Emerging Issues Task Force Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" ("EITF 07-3") that provides guidance for upfront payments related to goods and services of research and development costs. EITF 07-3 is effective for us beginning in 2008. Although the effect of this standard will depend primarily on arrangements existing in specific transactions, we do not believe that the implementation of EITF 07-3 will have a material impact on our results of operations and financial condition based on existing arrangements.

#### ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to various market risks, which are potential losses arising from adverse changes in market rates and prices, such as interest rates and foreign exchange fluctuations. We may enter into derivatives or other financial instruments for trading or speculative purposes; however, our policy is to only enter into contracts that can be designated as normal purchases or sales.

#### **Interest Rate Risk**

Borrowings under our revolving line of credit bear interest at a variable rate equal to SVB's prime rate. Borrowings under the equipment line bear interest at a variable rate equal to SVB's prime rate plus 1.0%. We currently do not use interest rate swaps to mitigate the impact of fluctuations in interest rates. As of December 31, 2007, we had no borrowings under our revolving line of credit and had \$10.0 million in borrowings under the equipment line. Based upon this debt level, a 10% increase in the interest rate on such borrowings would cause us to incur an increase in interest expense of approximately \$83,000 on an annual basis.

At December 31, 2007, cash and short term investments were \$90.8 million. Based on our annualized average interest rate, a 10% decrease in the interest rate on such balances would result in a reduction in interest income of approximately \$427,000 on an annual basis.

## Foreign Currency Exchange Rate Risk

Fluctuations in the rate of exchange between the U.S. dollar and foreign currencies could adversely affect our financial results. Approximately 27% and 29% of our net sales in 2007 and 2006, respectively, were denominated in foreign currencies. Although we expect the percentage of net sales denominated in foreign currencies to decrease in 2008 compared to 2007 as a result of our acquisition of FoxHollow, we currently expect that net sales denominated in foreign currencies will continue to represent a significant percentage of our net sales in the future. Selling, marketing and administrative costs related to these sales are largely denominated in the same respective currency, thereby limiting our transaction risk exposure. However, for sales not denominated in U.S. dollars, if there is an increase in the rate at which a foreign currency is exchanged for U.S. dollars, it will require more of the foreign currency to equal a specified amount of U.S. dollars than before the rate increase. In such cases and if we price our products in the foreign currency, we will receive less in U.S. dollars than we did before the rate increase went into effect. If we price our products in U.S. dollars and competitors price their products in local currency, an increase in the relative strength of the U.S. dollar could result in our price not being competitive in a market where business is transacted in the local currency.

Approximately 76% and 71% of our net sales denominated in foreign currencies in 2007 and 2006, respectively, were derived from European Union countries and were denominated in the Euro. Additionally, we have significant intercompany receivables from our foreign subsidiaries, which are denominated in foreign currencies, principally the Euro and the Yen. Our principal foreign currency exchange rate risks therefore exist between the U.S. dollar and the Euro and between the U.S. dollar and the Yen. Fluctuations from the beginning to the end of any given reporting period result in the remeasurement of our foreign currency-denominated receivables and payables, generating currency transaction gains or losses that impact our non-operating income/expense levels in the respective period and are reported in other (income) expense, net in our consolidated financial statements. We recorded a \$2.9 million foreign currency exchange rate transaction gain in 2007 and a \$2.1 million foreign currency exchange rate transaction gain in 2006, related to the translation of our foreign denominated net receivables into U.S. dollars. We do not currently hedge our exposure to foreign currency exchange rate fluctuations. We may, however, hedge such exposure to foreign currency exchange rates in the future.

# ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005	F-8
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#### MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

As management of ev3 Inc., we are responsible for establishing and maintaining an adequate system of internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended, for ev3 Inc. and its subsidiaries. This system is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

ev3's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of ev3; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of ev3 are being made only in accordance with authorizations of management and directors of ev3; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of ev3's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements and even when determined to be effective, can only provide reasonable assurance with respect to financial statement preparation and presentation. Also, projection of any evaluation of the effectiveness of internal control over financial reporting to future periods is subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate.

With our participation, management evaluated the effectiveness of ev3's internal control over financial reporting as of December 31, 2007. In making this evaluation, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control — Integrated Framework. This evaluation did not include the internal controls of FoxHollow Technologies, Inc. as of December 31, 2007. On October 4, 2007, we completed our acquisition of FoxHollow Technologies, Inc. Pursuant to guidance issued by the SEC, a company can exclude an acquired business's internal controls from management's report on internal control over financial reporting in the first year of acquisition. FoxHollow Technologies, Inc. is a wholly owned subsidiary of ours included in our consolidated financial statements and constituted less than 10 percent of our total assets at December 31, 2007, approximately 10 percent of our revenue and approximately 12 percent of net loss for the year then ended. Based on our evaluation under the COSO framework, management concluded that ev3's internal control over financial reporting (excluding FoxHollow) was effective as of December 31, 2007.

Ernst & Young LLP, ev3's independent registered public accounting firm, audited the effectiveness of ev3's internal control over financial reporting as of December 31, 2007 and, based on that audit, issued the report which is included elsewhere in this report.

/s/ James M. Corbett

/s/ Patrick D. Spangler

James M. Corbett

Chairman, President and Chief Executive Officer

Patrick D. Spangler Senior Vice President and Chief Financial Officer

March 12, 2008

Further discussion of our internal controls and procedures is included in Item 9A of this report, under the heading "Item 9A. Controls and Procedures."

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders ev3 Inc.

We have audited ev3 Inc.'s internal control over financial reporting as of December 31, 2007 based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). ev3 Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on ev3 Inc.'s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As indicated in the accompanying Management's Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of FoxHollow Technologies, Inc., which is included in the December 31, 2007, consolidated financial statements of ev3 Inc. and constituted less than 10 percent of total assets at December 31, 2007, approximately 10 percent of revenue and approximately 12 percent of net loss for the year then ended. Our audit of internal control over financial reporting of ev3 Inc. also did not include an evaluation of the internal control over financial reporting of FoxHollow Technologies, Inc.

In our opinion, ev3 Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of ev3 Inc. as of December 31, 2007 and 2006, and the related consolidated statements of operations, members' and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2007 of ev3 Inc. and our report dated March 12, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Minneapolis, Minnesota March 12, 2008

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders ev3 Inc.

We have audited the accompanying consolidated balance sheets of ev3 Inc. and subsidiaries as of December 31, 2007 and 2006, and the related consolidated statements of operations, members' and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2007. Our audit also included the financial statement schedule listed in Item 15. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of ev3 Inc. and subsidiaries at December 31, 2007 and 2006, and the consolidated results of their operations and their cash flows for each of the two years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth herein.

As discussed in Note 2, Summary of Significant Accounting Policies, to the consolidated financial statements, effective January 1, 2006 the Company adopted Statement of Financial Accounting Standards No. 123(R), "Share Based Payment". Also as discussed in Note 2, Summary of Significant Accounting Policies, effective January 1, 2007, the Company adopted FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109."

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), ev3 Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 12, 2008 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Minneapolis, Minnesota March 12, 2008

# Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of ev3 Inc.:

In our opinion, the consolidated statements of operations, members' and stockholders' equity (deficit) and cash flows for the year ended December 31, 2005 present fairly, in all material respects, the results of operations and cash flows of ev3 Inc. and its subsidiaries for the year ended December 31, 2005, in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule for the year ended December 31, 2005 presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audit. We conducted our audit of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Minneapolis, Minnesota March 3, 2006

# CONSOLIDATED BALANCE SHEETS (Dollars in thousands, except per share/unit amounts)

	Decemb	er 31,
•	2007	2006
ASSETS		
Current assets		•
Cash and cash equivalents	\$ 81,060	\$ 24,053
Short-term investments	9,744	14,700
Accounts receivable, less allowance of \$6,783 and \$3,924 respectively	66,170	45,137
Inventories	64,044	42,124
Prepaid expenses and other assets	6,371	7,162
Other receivables	981	2,669
Total current assets	228,370	135,845
Restricted cash	2,204	2,022
Property and equipment, net	37,985	24,072
Goodwill	586,648	149,061
Other intangible assets, net	231,000	40,014
Other assets	899	1,812
Total assets'	<u>\$1,087,106</u>	\$ 352,826
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 21,511	\$ 13,140
Accrued compensation and benefits	35,301	. 16,382
Accrued liabilities	49,429	10,102
Deferred revenue	9,347	_
Current portion of long-term debt	3,571	2,143
Total current liabilities	119,159	41,767
Long-term debt	6,429	5,357
Other long-term liabilities	3,037	468
Total liabilities	128,625	47,592
Stockholders' equity		
Common stock, \$0.01 par value, 300,000,000 shares authorized, 105,078,769 and 57,594,742 shares issued and outstanding as of December 31, 2007 and 2006,		
respectively	1,051	576
Additional paid in capital	1,739,064	919,221
Accumulated deficit	(781,039)	(614,578)
Accumulated other comprehensive income	(595)	15
Total stockholders' equity	958,481	305,234
Total liabilities and stockholders' equity	\$1,087,106	\$ 352,826

ev3 Inc.

CONSOLIDATED STATEMENTS OF OPERATIONS (Dollars in thousands, except per share/unit amounts)

	For the	nber 31,	
	2007	2006	2005
Sales			
Product sales	\$ 278,226	\$ 202,438	\$ 133,696
Research collaboration	5,957		
Net sales	284,183	202,438	133,696
Operating expenses:			
Product cost of goods sold	99,879	71,321	55,094
Research collaboration	1,065	_	_
Sales, general and administrative	195,267	141,779	130,427
Research and development	48,413	26,725	39,280
Amortization of intangible assets	20,306	17,223	10,673
(Gain) loss on sale of assets, net	(978)	162	200
Acquired in-process research and development	70,700	1,786	868
Special charges	19,054	<del>_</del>	
Total operating expenses	453,706	258,996	236,542
Loss from operations	(169,523)	(56,558)	. (102,846)
Other (income) expense:			
Loss (gain) on sale of investments, net	116	(1,063)	(4,611)
Interest (income) expense, net	(1,910)	(1,695)	9,916
Minority interest in loss of subsidiary	_		(2,013)
Other (income) expense, net	(2,934)	(2,117)	3,360
Loss before income taxes	(164,795)	(51,683)	(109,498)
Income tax expense	949	688	526
Net loss	(165,744)	(52,371)	(110,024)
Accretion of preferred membership units to redemption value			12,061
Net loss attributable to common share/unit holders	\$ (165,744)	\$ (52,371)	\$ (122,085)
Net loss per common share/unit (basic and diluted)(a)	\$ (2.37)	\$ (0.93)	\$ (4.48)
Weighted average shares/units outstanding (basic and			
diluted)(a)	69,909,708	56,585,025	27,242,712

<sup>(</sup>a) Net loss per common share/unit attributable to common holders and the weighted average common shares outstanding reflect the June 21, 2005 1-for-6 reverse stock split.

ev3 Inc.

# CONSOLIDATED STATEMENTS OF MEMBERS' AND STOCKHOLDERS' EQUITY (DEFICIT)

(Dollars in thousands, except per share/unit amounts)

		Members'	Common S			Accumulated Other Comprehensive		Total Members' and Stockholders' Equity
	Units	Capital	Shares	Amount	APIC	Income (Loss)	Deficit	(Deficit)
Balance as of January 1, 2005 Accretion of preferred membership	15,293,490	\$ 47,927	_	<b>\$</b> —	<b>\$</b> —	\$(1,694)	\$(440,705)	\$(394,472)
units	_		_	_		_	(12,061)	(12,061)
Compensation expense on options		1,309	40.100	_	3,530		· —	4,839
Exercise of options	502,140	660	49,193	$\frac{}{2}$	430		_	1,090
Restricted stock grant	3,004,332	8,404	185,000		(2)	_	_	8,404
Conversion of preferred/common	5,004,552	0,404			_			0,101
membership units	(18.799.962)	(58,300)	83.918.016	839	323,550	_		266,089
1-for-6 reverse common stock split			(69,931,666)	(699)	699		-	· —
Contribution of demand notes	_	_	23,159,304	231	323,999		_	324,230
Common stock issued in conjunction				400	154006			154.046
with initial public offering	_	_	11,970,800	120	154,826	_		154,946
Comprehensive loss:							(110,024)	(110,024)
Net loss						1,831	(110,024)	1,831
adjustment						1,051		1,051
percentage of MTI			_	_	_	-	583	583
Comprehensive loss								(107,610)
Balance December 31, 2005	_	\$ —	49,350,647	\$ 493	\$ 807,032	<b>\$ 137</b>	\$(562,207)	\$ 245,455
Compensation expense on options and					. <del></del>		•	( 7(0
restricted stock	_	_	1.160.594		6,760	-	_	6,760 9,936
Exercise of options		_	6,997,354	12 70	9,924 95,368		_	95,438
MTI acquisition	_	_	28,341		393		_	393
Restricted stock grant		_	74,024	1	(1)		_	
Shares repurchased	_	_	(16,218)		(255)		_	(255)
Comprehensive loss: Net loss			,		;	_	(52,371)	(52,371)
Cumulative translation adjustment						(122)	_	(122)
Comprehensive loss						(,		(52,493)
=		<u>*                                    </u>	57,594,742	¢ 576	¢ 010 221	\$ 15	\$(614,578)	
Balance December 31, 2006 Cumulative effect of adoption of	_	<b>э</b> —	31,394,144	<b>3</b> 5/0	\$ 919,221 	<b>3</b> 13	(717) (717)	
FIN 48	_	_	-	_	_	_	(/1/)	(111)
with secondary offering	_		2,500,000	25	44,517	_		44,542
Compensation expense on equity					·			
awards and stock purchase plan	_	_	=	_	11,127	_	<u> </u>	11,127
Exercise of options	_	_	664,178	7	6,719	•	_	6,726
Restricted stock grants, net of			1 176 221	12	(12)	•		
cancellations	_	_	1,176,321	12	(12)	_		_
		_	60,534	_	868		_	868
employee stock purchase plan Shares repurchased	_	_	(33,258)	) —	(507)	· —	_	(507)
Common stock issued in								
acquisition of FoxHollow	·—	_	43,118,667	431	757,131	-	_	757,562
FoxHollow stock transactions, other	_	_	(2,415)	) —	_	_	_	-
Comprehensive loss:  Net loss				•		_	(165,744)	(165,744)
Changes in unrealized gains (losses) on investments						(174)	_	(174)
Cumulative translation						()		` ,
adjustment						(436)	_	(436)
Comprehensive loss								(166,354)
Balance December 31, 2007		<u>\$</u>	105,078,769	\$1,051	\$1,739,064	\$ (595)	\$(781,039)	\$ 958,481
•						===		

ev3 Inc.

# CONSOLIDATED STATEMENTS OF CASH FLOWS (Dollars in thousands, except per share/unit amounts)

	For the Years Ended December 31		
	2007	2006	2005
Operating activities			
Net loss	\$(165,744)	\$(52,371)	\$(110,024)
Adjustments to reconcile net loss to net cash used in operating activities			·
Depreciation and amortization	28,726	22,878	14,816
Provision for bad debts and sales returns	2,024	728	650
Provision for inventory obsolescence	8,308	3,787	4,037
Acquired in-process research and development	70,700	1,786	868
(Gain) loss on disposal of assets	(978)	162	200
Gain on sales of investments	_	(1,063)	(4,611)
Stock compensation expense	11,127	7,153	4,873
Minority interest in loss of subsidiary	_	_	(2,013)
Change in operating assets and liabilities, net of acquired:		•	
Accounts receivable	1,340	(17,362)	(10,477)
Inventories	(14,524)	(12,287)	(14,712)
Prepaids and other assets	2,836	(619)	4,177
Accounts payable	3,060	1,186	3,804
Accrued expenses and other liabilities	(5,408)	(890)	. 882
Deferred revenue	9,347		
Accrued interest demand notes payable			(24,319)
Net cash used in operating activities	(49,186)	(46,912)	(131,849)
Investing activities			
Purchase of short-term investments		(6,750)	(12,000)
Proceeds from sale of short-term investments	6,900	4,050	_
Purchase of property and equipment	(13,804)	(11,983)	(13,216)
Purchase of patents and licenses	(3,270)	(3,516)	(1,677)
Purchase of distribution rights	(6,500)		
Proceeds from sale of assets	2,035	69	17
Proceeds from sale of investments	_	1,063	4,611
Acquisitions, net of cash acquired		(70)	(5,703)
Payments for the acquisition of FoxHollow, net of cash acquired	65,556	_	_
Return of acquisition consideration	_	_	2,124
Increase (decrease) in restricted cash	1,007	1,116	(266)
Other			841
Net cash provided by (used in) investing activities	51,924	(16,021)	(25,269)

	For the Yea	ember 31,	
•	2007	2006	2005
Financing activities			
Proceeds from issuance of common stock, net	\$ 44,542	\$ —	\$
Proceeds from initial public offering, net	_	_	154,946
Issuance of demand notes payable	_	_	49,100
Proceeds from long-term debt	5,000	7,500	
Payments on long-term debt	(2,499)	• —	_
Payments on capital lease obligations	(139)	(123)	(29)
Proceeds from exercise of stock options	6,726	9,936	1,090
Proceeds from issuance of subsidiary stock to minority shareholders	_	_	1,041
Proceeds from term financing	_	_	600
Debt issuance costs	_	(118)	
Proceeds from employee stock purchase plan	868		_
Other	(507)	(255)	
Net cash provided by financing activities	53,991	16,940	206,748
Effect of exchange rate changes on cash	278	454	(169)
Net increase (decrease) in cash and cash equivalents	57,007	(45,539)	49,461
Cash and cash equivalents, beginning of period	24,053	69,592	20,131
Cash and cash equivalents, end of period	\$ 81,060	\$ 24,053	\$ 69,592
Supplemental cash flow information:			•
Cash paid for interest	\$ 1,400	\$ 626	\$ 36,581
Cash paid for income taxes	\$ 610	\$ 570	\$ 24
Supplemental non-cash disclosure:		•	
Financed insurance premiums (see Note 19)	<b>\$</b>	\$ 3,500	\$ —
Net assets acquired in conjunction with the acquisition of FoxHollow (see			_
Note 4)			\$ —
Earn-out payment accrued (see Note 19)		•	\$ <u> </u>
Net assets acquired in conjunction with MTI step acquisition (see Note 4)	\$ <u> </u>	\$ 95,438	\$ 8,404
Contribution of demand notes payable upon initial public offering (see Note 12)	s –	\$ <b>—</b>	\$324,230
Preferred membership units converted to common stock upon initial public offering (see Note 15)	\$ <b>-</b>	<b>\$</b> —	\$266,089
·			

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

# 1. Organization and Description of Business

ev3 Inc. ("we," "our" or "us") is a global medical device company focused on catheter-based technologies for the endovascular treatment of vascular diseases and disorders. We develop, manufacture and market a wide range of products that include stents, atherectomy and thrombectomy products, balloon angioplasty catheters, microcatheters and occlusion balloon systems, embolic protection devices, infusion catheters/wires, embolic coils and liquid embolics. We market our products in the United States, Europe, Canada and other countries through a direct sales force and through distributors in certain other international markets and in the United States.

We were formed as ev3 LLC in September 2003 to hold the ownership interests of two companies: ev3 Endovascular, Inc. ("Endovascular") and Micro Investment, LLC ("MII"), a holding company that owned a controlling interest in Micro Therapeutics, Inc. ("MTI") at the time of formation. At the time of ev3 LLC's formation, MTI was a publicly traded operating company. ev3 LLC's majority equity holder, Warburg, Pincus Equity Partners, L.P. and certain of its affiliates ("Warburg Pincus"), owned a majority, controlling interest in both Endovascular and MII at the time of formation. In accordance with Financial Accounting Standards Board Statement ("SFAS") 141, Business Combinations and Financial Technical Bulletin ("FTB") 85-5, Issues related to Accounting for Business Combinations, ev3 LLC accounted for the transaction as a combination of entities under common control. The combination was accounted for on a historical cost basis as the ownership interests in the combining companies were substantially the same before and after the transaction. On January 28, 2005, we were formed as a subsidiary of ev3 LLC. Immediately prior to the consummation of our initial public offering on June 21, 2005, ev3 LLC was merged with and into us, and we became the holding company for all of ev3 LLC's subsidiaries.

Prior to the consummation of our initial public offering on June 21, 2005, we amended and restated our certificate of incorporation to authorize 100,000,000 shares of common stock, par value \$0.01 per share, and 100,000,000 shares of preferred stock, par value \$0.01 per share. On June 21, 2005, immediately prior to our initial public offering, we completed a one-for-six reverse stock split of our outstanding common stock. All share/unit and per share/unit amounts for all periods presented in these consolidated financial statements reflect this split.

On May 26, 2005, Warburg Pincus and The Vertical Group, L.P. and certain of its affiliates ("Vertical") contributed all of their shares of MTI's common stock to ev3 LLC in exchange for common membership units. In accordance with SFAS 141, the contribution of the shares by Warburg Pincus is accounted for as a transfer of assets between entities under common control, resulting in the retention of historical based accounting. These consolidated financial statements give effect to the contribution of MTI shares owned by Warburg Pincus as though such contribution occurred in 2003 and 2004 when Warburg Pincus acquired its interest in MTI. The contribution of the MTI shares by Vertical has been accounted for under the purchase method of accounting on the contribution date. As described in Note 4, on January 6, 2006, we acquired the 30% minority interest of MTI through a merger of MII with and into MTI. MTI was the surviving entity and, as a result of this merger, became our wholly owned subsidiary.

On October 4, 2007, we completed our acquisition of FoxHollow Technologies, Inc. ("FoxHollow"), a medical device company that designs, develops, manufactures and sells medical devices primarily for the treatment of peripheral artery disease, or PAD. FoxHollow is also engaged in a research collaboration with Merck & Co., Inc. ("Merck") for the analysis of atherosclerotic plaque removed from patient arteries with the goal of identifying new biomarkers for atherosclerotic disease progression and new therapies for atherosclerotic disease. Following completion of the acquisition, FoxHollow became a wholly owned subsidiary of ev3. In connection with our acquisition of FoxHollow, we amended and restated our certificate of incorporation to increase the number of authorized shares from 100 million to 300 million shares of common stock.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

# 2. Summary of Significant Accounting Policies

#### Principles of Consolidation

The consolidated financial statements include our accounts and the accounts of our wholly owned subsidiaries and other subsidiaries in which we maintain a controlling interest. All significant intercompany balances and transactions have been eliminated. At December 31, 2006, MTI was a wholly owned subsidiary (see Note 4). At December 31, 2005, there was a minority interest of 30% in MTI. Prior to our acquisition of the remaining outstanding shares of MTI that we did not already own, the minority shareholders of MTI had the right to receive their proportionate share of MTI's equity and in turn absorb a proportionate share of MTI's losses. On October 4, 2007, we merged with FoxHollow and FoxHollow became a wholly owned subsidiary (see Note 4).

# Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts and disclosures in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

# Cash Equivalents

We consider highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents. These investments are stated at cost, which approximates fair market value.

#### Short-term Investments

We classify all investments with average maturities of less than one year as "available-for-sale." Such investments are recorded at fair value and unrealized gains and losses are recorded in stockholders' equity (deficit), as a component of other comprehensive loss, until realized. Realized gains and losses on the sale of all such securities are reported in net loss, computed using the specific identification cost method.

#### Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. We make judgments as to our ability to collect outstanding receivables and provide an allowance for credit losses when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding account balances and the overall quality and age of those balances not specifically reviewed. In determining the allowance required, we analyze historical collection experience and current economic trends. If the historical data used to calculate the allowance for doubtful accounts does not reflect our future ability to collect outstanding receivables or if the financial condition of customers were to deteriorate, resulting in impairment of their ability to make payments, an increase in the provision for doubtful accounts may be required.

#### Inventories

Inventories are stated at the lower of cost or market value, determined on a first-in, first-out basis.

We calculate an inventory reserve for estimated obsolescence or excess inventory based on historical turnover and assumptions about future demand for our products and market conditions which includes estimates of the impact of the introduction of new or enhanced products on existing inventory. Our industry is characterized by regular new product development, and as such, our inventory is at risk of obsolescence following the introduction and development of new or enhanced products. Our estimate and assumptions for

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

excess and obsolete inventory are reviewed and updated on a quarterly basis. The estimates we use for demand are also used for near-term capacity planning and inventory purchasing and are consistent with our sales forecasts. Future product introductions and related inventories may require additional reserves based upon changes in market demand or introduction of competing technologies. Increases in the reserve for excess and obsolete inventory result in a corresponding expense to cost of goods sold. In the fourth quarter of 2007, our excess and obsolete inventory reserves, included approximately \$3.3 million of adjustments for the planned discontinuance of the Primus balloon expandable stent and the Sailor .035 balloon due to our strategic marketing focus on new product introductions.

#### Restricted Cash

Restricted cash consists of various deposits supporting credit arrangements and security deposits for our building leases.

# Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Additions and improvements that extend the lives of assets are capitalized, while expenditures for repairs and maintenance are expensed as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Amortization of capital leases and leasehold improvements is provided on a straight-line basis over the estimated lives of the related assets or the life of the lease, whichever is shorter, and generally ranges from three to seven years. Machinery and other equipment are depreciated over three to 10 years, computer hardware and software are depreciated over three to five years, furniture and fixtures over five to seven years. Construction in process is not depreciated until the related asset is placed in service.

#### Goodwill

We evaluate the carrying value of goodwill during the fourth quarter of each year and between annual evaluations if events occur or circumstances change that indicate that the carrying amount of goodwill may be impaired. We have two reporting units: Peripheral Vascular, which includes our acquisition of FoxHollow, and Neurovascular, the same as our operating segments. When evaluating whether goodwill is impaired, the fair value of the reporting unit to which the goodwill is assigned is compared to its carrying amount, including goodwill. If the carrying amount of a reporting unit exceeds its fair value, then the amount of the impairment loss must be measured. The impairment loss, if any, is calculated by comparing the implied fair value of reporting unit goodwill to its carrying amount. Fair value of the reporting unit is based on various valuation techniques, including the discounted value of estimated future cash flows.

# Impairment of Long-Lived Assets and Amortizable Intangible Assets

Long-lived assets such as property, equipment, and intangible assets are reviewed for impairment when events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when estimated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. Where available, quoted market prices are used to determine fair market value. When quoted market prices are not available, various valuation techniques, including the discounted value of estimated future cash flows, are utilized.

# Investments

We have made certain strategic investments in companies of less than 20% of their outstanding equity interests, and in various stages of development and account for these investments under the cost method of accounting. The valuation of investments accounted for under the cost method is based on all available financial information related to the investee, including valuations based on recent third party equity

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - (Continued)

investments in the investee. If an unrealized loss on any investment is considered to be other-than-temporary, the loss is recognized in the period the determination is made. All investments are reviewed for changes in circumstances or occurrence of events that suggest our investment may not be recoverable.

## Revenue Recognition

We sell the majority of our products via direct shipment to hospitals or clinics. Sales are made through our direct sales force, distributors or through consignment arrangements with hospitals and clinics. We recognize revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sales price is fixed or determinable; and collectibility is reasonably assured. These criteria are met at the time of shipment when the risk of loss and title passes to the customer or distributor, unless a consignment arrangement exists. Revenue from consignment arrangements is recognized when we receive written notification from the hospital or clinic that the product has been used. We record estimated sales returns, discounts and rebates as a reduction of net sales in the same period revenue is recognized.

Sales to distributors are recognized at the time of shipment, provided that we have received an order, the price is fixed or determinable, collectibility of the resulting receivable is reasonably assured and we can reasonably estimate returns. Non-refundable fees received from distributors upon entering into multi-year distribution agreements, where there is no culmination of a separate earnings process, are deferred and amortized over the term of the distribution agreement or the expected period of performance, whichever is longer.

Costs related to products delivered are recognized in the period revenue is recognized. Cost of goods sold consists primarily of direct labor, allocated manufacturing overhead, raw materials and components and excludes the amortization of intangible assets.

## Deferred Revenue

In conjunction with our acquisition of FoxHollow on October 4, 2007, we assumed all rights and obligations associated with an Amended and Restated Collaboration and License Agreement ("Collaboration and License Agreement") with Merck. Under the Collaboration and License Agreement, we are obligated to grant Merck certain exclusive rights and to perform certain research activities under Merck's direction, including removal of atherosclerotic plaque from patient arteries for analysis, conduct of clinical trials and drug profiling by Merck. The revenue streams for the Collaboration and License Agreement include a minimum of \$60.0 million in aggregate for collaboration for three years beginning November 2006 and a total of \$40.0 million in license/exclusivity payments for four years beginning on the same date. Both the collaboration and license components are accounted for as a single unit of accounting under Emerging Issues Task Force Issue No. 00-21 ("EITF 00-21"), Accounting for Revenue Arrangements with Multiple Deliverables and SAB No. 104. The revenue is recognized on a straight-line basis over the four-year term of the license/exclusivity portion of the Collaboration and License Agreement and further limited to cumulative amounts due and collected at any point under the arrangement. This has resulted in the recording of deferred revenue for cash collected in excess of revenue recognized of \$9.3 million at December 31, 2007.

## Shipping and Handling Costs

All shipping and handling costs are expensed as incurred and recorded as a component of sales, general and administrative expense in the consolidated statement of operations. Such expenses for the years ended December 31, 2007, 2006 and 2005 were approximately \$2.9 million, \$2.5 million and \$2.2 million, respectively. Shipping and handling amounts, if any, billed to customers are included in net product sales.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

## **Advertising Costs**

All advertising costs are expensed as incurred. We market our products primarily through a direct sales force and advertising expenditures are not material.

## Research and Development

Research and development costs are expensed as incurred and include the costs to design, develop, test, deploy and enhance our products. It also includes costs related to the execution of clinical trials and costs incurred to obtain regulatory approval for our products.

## Acquired In-process Research and Development ("IPR&D")

When we acquire another company or group of assets, the purchase price is allocated, as applicable, between IPR&D, net tangible assets, goodwill and other intangible assets. We define IPR&D as the value assigned to those projects for which the related products have not received regulatory approval and have no alternative future use. Determining the portion of the purchase price allocated to IPR&D requires us to make significant estimates. The amount of the purchase price allocated to IPR&D is determined by estimating the future cash flows of each project or technology and discounting the net cash flows back to their present value. The discount rate used is determined at the time of the acquisition and includes consideration of the assessed risk of the project not being developed to a stage of commercial feasibility. Amounts allocated to IPR&D are expensed at the time of acquisition.

## Foreign Currency Translation

The local currency is generally designated as the functional currency for our international operations. Accordingly, assets and liabilities are translated into U.S. Dollars at year-end exchange rates, and revenues and expenses are translated at average exchange rates prevailing during the year. Currency translation adjustments resulting from fluctuations in exchange rates are recorded in other comprehensive income.

Gains and losses on foreign currency transactions are included in "other (income) expense" in the consolidated statements of operations. Foreign currency transactions resulted in transaction gains of \$2.9 million for the year ended December 31, 2007, transaction gains of \$2.1 million for the year ended December 31, 2006, and transaction losses of \$3.6 million for the year ended December 31, 2005.

#### Income Taxes

We account for income taxes under the liability method pursuant to the provisions of Statement of Financial Accounting Standards No. 109 "Accounting for Income Taxes" (SFAS 109). Deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year end, based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable earnings. Valuation allowances are established when necessary to reduce deferred tax assets to the amount that is more likely than not to be realized. The effect of changes in tax rates is recognized in the period in which the rate change occurs.

On January 1, 2007, we adopted FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" (FIN 48). FIN 48 clarifies when tax benefits should be recorded in financial statements, requires certain disclosures of uncertain tax matters and indicates how any tax reserves should be classified in a balance sheet. As a result of adopting this standard, we recorded a charge of \$717,000, which was accounted for as an increase to the January 1, 2007 balance of accumulated deficit.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (Continued)

## Loss per Membership Share/Unit

Basic loss per membership share/unit (referred to as "share" hereafter) is computed based on the weighted average number of common shares outstanding. Diluted loss per share is computed based on the weighted average number of common shares outstanding adjusted, to the extent dilutive, by the number of additional shares that would have been outstanding had the potentially dilutive common shares been issued and reduced by the number of shares we could have repurchased with the proceeds from the potentially dilutive shares. Potentially dilutive shares include share options and other share-based awards granted under share-based compensation plans. For the years ended December 31, 2007, 2006 and 2005, all potential common shares were anti-dilutive. Accordingly, diluted loss per share is equivalent to basic loss per share.

## Comprehensive Loss

Comprehensive loss consists of net loss, the effects of foreign currency translation, unrealized gain (loss) on available for sale investments and, prior to fiscal 2006, gains on changes of interest related to ownership changes in MTI.

#### Concentrations of Credit Risk

Financial instruments that potentially subject us to credit risk consist principally of cash, cash equivalents, investments, and accounts receivable.

We maintain cash and cash equivalents with various major financial institutions, however we are exposed to credit risk in the event of default by these financial institutions for amounts in excess of Federal Deposit Insurance Corporation insured limits. We perform periodic evaluations of the relative credit standings of these financial institutions and attempt to limit the amount of credit exposure with any one institution by maintaining accounts at multiple institutions. Management believes that the our investments in cash, cash equivalents and investments are financially sound and have minimal credit risk.

We have a credit policy and perform ongoing credit evaluations of our customers. We do not generally require collateral or other security and maintain an allowance for potential credit losses. Management believes this risk is limited due to the large number and diversity of hospitals and distributors who comprise our customer base.

#### Accounting for Stock-Based Compensation

On January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment" (SFAS 123(R)) using the modified prospective method. SFAS 123(R) requires companies to measure and recognize the cost of employee services received in exchange for awards of equity instruments based on the grant date fair value of those awards. Compensation cost under SFAS 123(R) is recognized ratably using the straight-line attribution method over the expected vesting period, which is considered to be the requisite service period. In addition, pursuant to SFAS 123(R), we are required to estimate the amount of expected forfeitures when calculating the compensation costs, instead of accounting for forfeitures as incurred, which was our previous method. All of our options previously awarded were classified as equity instruments and continue to maintain their equity classification under SFAS 123(R).

Prior to January 1, 2006 and since the beginning of 2003, we accounted for share-based awards under the recognition provisions of SFAS 123, "Accounting for Stock-Based Compensation" using the modified prospective method of adoption described in SFAS 148. We used the minimum value pricing model for measuring the fair value of our options granted through the first quarter 2005, which does not take into consideration volatility. In accordance with SFAS 123, subsequent to April 5, 2005, the date of our initial filing of the registration statement relating to our initial public offering with the Securities and Exchange Commission, we used the Black-Scholes method, including an estimated volatility assumption, to estimate the

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

fair value of all option grants. Expense previously recognized related to options that were cancelled or forfeited prior to vesting was reversed in the period of the cancellation or forfeiture, as allowed under SFAS 123.

The fair value of options are estimated at the date of grant using the Black-Scholes option pricing model with the assumptions listed below. Risk free interest rate is based on U.S. Treasury rates appropriate for the expected term. Expected volatility and forfeiture rates are based on a combination of historical factors related to our common stock since our June 2005 initial public offering and the volatility rates of a set of guideline companies. The guideline companies consist of public and recently public medical technology companies. Dividend yield is zero as we do not expect to declare any dividends in the foreseeable future. The expected term is based on the weighted average time between grant and employee exercise. The fair value of stock granted to employees is based upon the closing market value of our common stock on the date of grant. The key assumptions used in estimating the fair value of our stock-based compensation awards were as follows:

	Year Ended December 31,						
·	2007	2006		2007 2006 2005		)05	
	ev3 Inc.	ev3 Inc.	ev3 Inc.	MTI			
Risk free interest rate	4.4%	4.7%	3.8%	4.0%			
Expected dividend yield	0.0%	0.0%	0.0%	0.0%			
Expected volatility	43.6%	49.1%	50.0%	56.0%			
Expected option term	3.85 years	3.75 years	4 years	4 years			

In accordance with the provisions of SFAS 123(R) and Emerging Issues Task Force Issue 96-18, "Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," we account for non-employee equity-based awards, in which goods or services are the consideration received for the equity instruments issued, at their fair value.

The following table summarizes the stock-based compensation expense (in thousands) for employees and non-employees recognized in the income statement for each period:

•		Year Ended December 31,			
		2007	2006	2005	
Stock Based Compensation Charges:					
Product cost of goods sold	\$	926	\$ 630	\$ 653	
Sales, general and administrative		8,832	5,868	3,141	
Research and development		1,369	655	1,079	
Total Stock Based Compensation Charges	\$1	1,127	<u>\$7,153</u>	\$4,873	

#### Fiscal Year

We operate on a manufacturing calendar with our fiscal year always ending on December 31. Each quarter is 13 weeks, consisting of one five-week and two four-week periods.

## New Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141 (Revised 2007) "Business Combinations" and SFAS No. 160 "Non-controlling Interests in Consolidated Financial Statements," which are effective for fiscal years beginning after December 15, 2008. These new standards represent the completion of the FASB's first major joint project with the International Accounting Standards Board (IASB) and are intended to improve, simplify, and converge internationally the accounting for business combinations and the reporting of noncontrolling interests (formerly minority interests) in consolidated financial statements. ev3 will adopt these

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

standards at the beginning of its 2009 fiscal year. The effect of adoption will generally be prospectively applied to transactions completed after the end of the Company's 2008 fiscal year, although the new presentation and disclosure requirements for pre-existing non-controlling interests will be retrospectively applied to all prior-period financial information presented.

SFAS No. 141(R) retains the underlying fair value concepts of its predecessor (SFAS No. 141), but changes the method for applying the acquisition method in a number of significant respects including the requirement to expense transaction fees and expected restructuring costs as incurred, rather than including these amounts in the allocated purchase price; the requirement to recognize the fair value of contingent consideration at the acquisition date, rather than the expected amount when the contingency is resolved; the requirement to recognize the fair value of acquired in-process research and development assets at the acquisition date, rather than immediately expensing; and the requirement to recognize a gain in relation to a bargain purchase price, rather than reducing the allocated basis of long-lived assets. Because this standard is generally applied prospectively, the effect of adoption on the Company's financial statements will depend primarily on specific transactions, if any, completed after 2008.

In September 2006, the FASB issued SFAS 157, "Fair Value Measurement." The standard provides guidance for using fair value to measure assets and liabilities. SFAS 157 clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. Under the standard, fair value measurements would be separately disclosed by level within the fair value hierarchy. The statement is effective for us beginning in 2008. In February 2008, the FASB issued FASB Staff Position (FSP) SFAS No. 157-2, "Effective Date of FASB Statement No. 157" (FSP SFAS No. 157-2) that deferred the effective date of SFAS No. 157 for one year for certain nonfinancial assets and nonfinancial liabilities. We do not believe that the implementation of SFAS 157 will have a material impact on our results of operations and financial condition.

In December 2007, the FASB issued SFAS 160, "Noncontrolling Interests in Consolidated Financial Statements." SFAS 160 establishes new standards that will govern the accounting for and reporting of noncontrolling interests in partially owned subsidiaries. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008 and requires retroactive adoption of the presentation and disclosure requirements for existing minority interests. All other requirements shall be applied prospectively. As of December 31, 2007, we do not have any partially owned consolidated subsidiaries and therefore, we do not expect an impact related to the adoption of this accounting standard.

On February 15, 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115" (SFAS No. 159). SFAS No. 159 creates a "fair value option" under which an entity may elect to record certain financial assets or liabilities at fair value upon their initial recognition. Subsequent changes in fair value would be recognized in earnings as those changes occur. The election of the fair value option would be made on a contract-by-contract basis and would need to be supported by concurrent documentation or a preexisting documented policy. SFAS No. 159 requires an entity to separately disclose the fair value of these items on the balance sheet or in the footnotes to the financial statements and to provide information that would allow the financial statement user to understand the impact on earnings from changes in the fair value. SFAS No. 159 is effective for us beginning in 2008. We do not believe that the implementation of SFAS 159 will have a material impact on our results of operations and financial condition.

In June 2006, the FASB issued Emerging Issues Task Force Issue No. 06-3, "How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement (That Is, Gross versus Net Presentation)" (EITF 06-3). EITF 06-3 indicates that the presentation of taxes within the scope of this issue on either a gross or net basis is an accounting policy decision that should be disclosed. Our

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

policy is to present the taxes collected from customers and remitted to governmental authorities on a net basis. These amounts are not material to our results of operations and financial condition.

In June 2007, the FASB issued Emerging Issues Task Force Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities" ("EITF 07-3") that provides guidance for upfront payments related to goods and services of research and development costs. EITF 07-3 is effective for us beginning in 2008. Although the effect of this standard will depend primarily on arrangements existing in specific transactions, we do not believe that the implementation of EITF 07-3 will have a material impact on our results of operations and financial condition based on existing arrangements.

## 3. Liquidity and Capital Resources

Since inception, we have generated significant operating losses. Historically, our liquidity needs have been met through a series of preferred investments, by demand notes payable issued to Warburg Pincus and Vertical and public equity offerings. On June 21, 2005, we completed an initial public offering in which we sold 11,765,000 shares of our common stock at \$14.00 per share for net cash proceeds of \$152.7 million, net of underwriting discounts and other offering costs. Immediately prior to the consummation of the offering, ev3 LLC merged with and into ev3 Inc. and 24,040,718 Class A preferred membership units, 41,077,336 Class B preferred membership units, and 18,799,962 common membership units of ev3 LLC were converted into 83,918,016 shares of common stock of ev3 Inc. (on a pre-split basis). Immediately thereafter, we completed a one-for-six reverse stock split whereby the 83,918,016 shares of common stock were converted into 13,986,350 shares of common stock. Prior to the consummation of the offering, and subsequent to the reverse stock split, we also issued 21,964,815 and 1,194,489 shares of common stock to Warburg Pincus and Vertical, respectively, in exchange for their contribution of \$324.2 million aggregate principal amount of demand notes and accrued and unpaid interest thereon. The remaining balance of the accrued and unpaid interest on the demand notes, totaling \$36.5 million, was repaid using proceeds from the offering. On July 20, 2005, we sold an additional 205,800 shares of common stock pursuant to the over-allotment option granted to the underwriters in connection with the initial public offering. Our net proceeds from this sale totaled \$2.2 million, after deducting underwriting discounts and other offering expenses. The total net cash proceeds we received from our initial public offering were \$154.9 million.

On June 28, 2006, our subsidiaries, ev3 Endovascular, Inc., ev3 International, Inc. and Micro Therapeutics, Inc. (collectively, the "Borrowers"), entered into a Loan and Security Agreement ("Loan Agreement") with Silicon Valley Bank ("SVB"), consisting of a two-year \$30.0 million revolving line of credit and a 48-month \$7.5 million equipment financing line. Pursuant to the terms of the Loan Agreement, and subject to specified reserves, we may borrow under the revolving line of credit up to \$12.0 million without any borrowing base limitations. Aggregate borrowings under the revolving line of credit that exceed \$12.0 million will subject the revolving line to borrowing base limitations. These limitations allow us to borrow, subject to specified reserves, up to 80% of eligible domestic and foreign accounts receivables plus up to 30% of eligible inventory. Additionally, borrowings against the eligible inventory may not exceed the lesser of 33% of the amount advanced against accounts receivable or \$7.5 million. Borrowings under the equipment advances bear interest at a variable rate per annum equal to SVB's prime rate plus 1.0%. The prime rate at December 31, 2007 was 7.25%. Accrued interest on any outstanding balance under the revolving line and the equipment financing advances is payable monthly in arrears. Amounts that were outstanding under the Equipment Advance A as of December 31, 2006 are payable in 42 consecutive equal monthly installments of principal, beginning on January 31, 2007. Amounts that were outstanding under the Equipment Advance B are payable in 42 equal monthly payments of principal, commencing on the last day of the seventh month following the date that the Equipment Advance B was made and continuing on the last day of each month thereafter until the last day of the 48th month following the date of such advance. As of December 31, 2007, we had \$5.4 million in outstanding borrowings under the Equipment Advance A and \$4.6 million in outstanding

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

borrowings under the Equipment Advance B and no outstanding borrowings under the revolving line of credit; however, we had approximately \$2.4 million of outstanding letters of credit issued by SVB, which reduces the maximum amount available under our revolving line of credit to approximately \$27.6 million.

Both the revolving line of credit and equipment financing are secured by a first priority security interest in substantially all of our assets, excluding intellectual property, which is subject to a negative pledge, and are guaranteed by ev3 Inc. and all of our domestic direct and indirect subsidiaries. The Loan Agreement requires the Borrowers to maintain a specified liquidity ratio. The Loan Agreement imposes certain limitations on the Borrowers, their subsidiaries and ev3 Inc., including without limitation, on their ability to: (i) transfer all or any part of their business or properties; (ii) permit or suffer a change in control; (iii) merge or consolidate, or acquire any entity; (iv) engage in any material new line of business; (v) incur additional indebtedness or liens with respect to any of their properties; (vi) pay dividends or make any other distribution on or purchase of, any of their capital stock; (vii) make investments in other companies; or (viii) engage in related party transactions, subject in each case to certain exceptions and limitations. The Loan Agreement requires us to maintain on deposit or invested with SVB or its affiliates the lesser of \$15.0 million or 50% of our aggregate cash and cash equivalents. The Borrowers are required to pay customary fees with respect to the facility, including a fee on the average unused portion of the revolving line of credit.

The Loan Agreement contains customary loan covenants and events of default, including the failure to make required payments, the failure to comply with certain covenants or other agreements, the occurrence of a material adverse change, failure to pay certain other indebtedness and certain events of bankruptcy or insolvency. Upon the occurrence and during the continuation of an event of default, amounts due under the Loan Agreement may be accelerated. As of December 31, 2007, we were in compliance with all loan covenants under the Loan Agreement.

On April 19, 2007, we completed a secondary public offering issuing 2,500,000 shares of our common stock which generated approximately \$44.5 million in net proceeds.

On October 4, 2007, we paid \$99.3 million in cash and direct acquisition costs to acquire FoxHollow. In this transaction, we acquired all of the outstanding shares of FoxHollow in exchange for 43,118,667 shares of our common stock, which is approximately 41% of the outstanding common stock of the combined company, with an estimated fair value of \$725.7 million. At the effective date and as a result of the acquisition, each share of common stock of FoxHollow issued and outstanding immediately prior to the effective date of the acquisition was converted into the right to receive 1.45 shares of our common stock and \$2.75 in cash. Alternatively, FoxHollow stockholders could have elected to receive either 1.62 shares of our common stock or \$25.92 in cash for each share of FoxHollow common stock by making an all-stock or an all-cash election, respectively. Stock and cash elections were subject to pro-ration to preserve an overall mix of 1.45 shares of our common stock and \$2.75 in cash for all of the outstanding shares of FoxHollow common stock in the aggregate.

Our future liquidity and capital requirements will be influenced by numerous factors, including the extent and duration of future operating losses, the level and timing of future sales and expenditures, the results and scope of ongoing research and product development programs, working capital to support our sales growth, receipt of and time required to obtain regulatory clearances and approvals, sales and marketing programs, continuing acceptance of our products in the marketplace, competing technologies, market and regulatory developments, acquisitions and the future course of intellectual property and other litigation. We believe that our cash, cash equivalents, short-term investments, anticipated cash from operations and current and anticipated financing arrangements will be sufficient to meet our liquidity requirements through at least the next 12 months. However, there is no assurance that additional funding will not be needed. In the event that we require additional working capital to fund future operations and any future acquisitions, we may sell shares of our common stock or other equity securities, sell debt securities, enter into additional credit and financing arrangements with one or more independent institutional lenders. If additional funding were needed, there is no assurance that such funding will be available to us or our subsidiaries on acceptable terms, or at all. If we

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

require additional working capital but are not able to raise additional funds, we may be required to significantly curtail or cease ongoing operations.

## 4. Acquisitions

## FoxHollow Acquisition

On October 4, 2007, we acquired FoxHollow Technologies, Inc., a medical device company that designs, develops, manufacturers and sells medical devices primarily for the treatment of peripheral artery disease. FoxHollow is also engaged in a research collaboration with Merck & Co., Inc. for the analysis of atherosclerotic plaque removed from patient arteries with the goal of identifying new biomarkers for atherosclerotic disease progression and new therapies for atherosclerotic disease. With the addition of FoxHollow we have created one of the leading companies focused on the treatment of peripheral and neurovascular disease. Our product portfolio now includes a broad spectrum of technologically advanced products to treat vascular disease in both the peripheral and neurovascular markets, which allows us to offer a more comprehensive and better integrated set of endovascular products to our customers.

We paid \$856.9 million to acquire FoxHollow through a combination of common stock, cash and fully vested and partially vested stock options and awards. In this transaction, we acquired all of the outstanding shares of FoxHollow in exchange for 43,118,667 shares of our common stock, which is approximately 41% of the outstanding common stock of the combined company, with an estimated fair value of \$725.7 million. At the effective date and as a result of the acquisition, each share of common stock of FoxHollow issued and outstanding immediately prior to the effective date of the acquisition was converted into the right to receive 1.45 shares of our common stock and \$2.75 in cash. Alternatively, FoxHollow stockholders could have elected to receive either 1.62 shares of our common stock or \$25.92 in cash for each share of FoxHollow common stock by making an all-stock or an all-cash election, respectively. Stock and cash elections were subject to pro-ration to preserve an overall mix of 1.45 shares of our common stock and \$2.75 in cash for all of the outstanding shares of FoxHollow common stock in the aggregate.

The fair value of the shares of our common stock issued as a result of the acquisition was \$16.83 per share based on the average trading price of our common stock for the two full trading days prior to and subsequent to the date of the announcement, July 22, 2007, as required under SFAS 141 and EITF No. 99-12, Determination of the Measurement Date for the Market Price of Acquirer Securities Issued in a Purchase Business Combination.

We paid \$81.8 million in cash and approximately \$17.5 million in direct acquisition costs including a payment of \$8.7 million to Merck under the terms and conditions of a stock purchase agreement. The purchase price net of cash acquired was approximately \$690.0 million and cash acquired was comprised of \$81.5 million of cash on hand and \$85.4 million of short-term investments.

At the effective time of the acquisition, each outstanding option to purchase shares of FoxHollow common stock and other awards based on FoxHollow common stock were converted into and became respectively an option to purchase 1.618 shares of our common stock or an award based on shares of our common stock. The number of shares of our common stock exchanged for FoxHollow options and awards was approximately 6,605,663 shares, with an estimated fair value of \$45.9 million, of which \$31.9 million relates to the vested portion of the options and therefore represents additional purchase price consideration and \$14.0 million relates to the unvested portion of the options which will be recognized as compensation cost over the remaining service period.

We determined the estimated fair value of the ev3 stock options and awards exchanged for FoxHollow options and awards was \$6.34. We used a Black-Scholes option-pricing model to determine the fair value of the exchanged options and awards. The determination of the fair value for the exchanged options and awards requires the use of significant estimates and assumptions which include the expected life of the award, the

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

expected stock price volatility over the expected life of the awards and the risk-free interest rate. A change in any of the estimates or assumptions used could significantly change the valuation and fair value of the options and awards. Our estimates and assumptions were based upon information that we believed to be reasonable as of the date of the acquisition. The following table presents the assumptions used to determine the fair value of the options and awards assuming no expected dividends:

Expected term (in years)	 2.7
Expected volatility	 45.00%
Risk-free interest rate	 4.60%
Stock price on date of grant	 \$16.83
Weighted-average exercise price	 \$14.99

There were no contingent payments, options or commitments specified in the ev3/FoxHollow merger agreement.

The following table presents the preliminary purchase price (in thousands) for the acquisition:

	Purchase Price Consideration
FoxHollow common shares converted	\$725,687
Cash consideration	81,811
FoxHollow options converted	31,875
Total cash and equity	\$839,373
Merck consideration	8,824
Deal costs	8,718
Total purchase price consideration	\$856,915

The acquisition has been accounted for under the purchase accounting method pursuant to SFAS 141. Our consolidated financial statements for the year ended December 31, 2007 include the financial results of FoxHollow subsequent to the acquisition date of October 4, 2007.

The aggregate FoxHollow purchase price was allocated to the assets acquired and liabilities assumed based on their preliminary estimated fair values at the date of the acquisition. The preliminary estimate of the excess of purchase price over the fair value of net tangible assets acquired was allocated to identifiable intangible assets and goodwill. In accordance with U.S. generally accepted accounting principles, we have up to 12 months from closing of the acquisition to finalize the valuation. The purchase price allocation is preliminary, pending finalization of our valuation of certain liabilities assumed, primarily related to restructuring activities and general reserves. The following table summarizes the preliminary estimate of fair value (in thousands) of the identifiable intangibles assets, goodwill and tangible assets, net of liabilities assumed, that were acquired as part of the acquisition with FoxHollow:

	2007
Intangible assets	\$199,500
Acquired in-process research and development	70,700
Tangible assets acquired, net of liabilities assumed	156,628
Goodwill	430,087
Estimated fair value of identifiable tangible and intangible assets and goodwill, net of cash acquired and liabilities assumed	\$856,915

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Weighted Average

The following table presents the identifiable intangible assets acquired, excluding goodwill, and the weighted average amortization period in total and by major intangible asset class:

Intangible Asset Description	Fair Value Assigned	Amortization Period (in years)
Developed and core technology	\$138,800	12
Customer relationships		12
Merck exclusivity	13,600	3.25
Trademarks and tradenames	7,100	10
Total intangible assets acquired (excluding goodwill)	\$199,500	11

The acquired in-process research and development charges were estimated using an appraisal and represent the estimated fair value of the in-process projects at the date of the acquisition. As of the date of the acquisition, the in-process projects had not yet reached technological feasibility and had no alternative use. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval to market the products. Accordingly, the value attributable to these projects, which had yet to obtain regulatory approval, was expensed in conjunction with the acquisition. If the projects are not successful, or completed in a timely manner, we may not realize the financial benefits expected from these projects.

The income approach was used to determine the fair value of the acquired in-process research and development. This approach establishes fair value by estimating the after-tax cash flows attributable to any in-process project over its useful life and then discounting these after-tax cash flows back to the present value. The costs to complete each project were based on estimated direct project expenses as well as the remaining labor hours and related overhead costs. In arriving at the value of acquired in-process research and development projects, we considered the project's stage of completion, the complexity of the work to be completed, the costs already incurred, and the remaining costs to complete the project, the contribution of core technologies, the expected introduction date and the estimated useful life of the technology. The discount rate used to arrive at the present value of acquired in-process research and development as of the date of the acquisition was based on the time value of money and medical technology investment risk factors. The discount rate used was approximately 14%.

During fiscal 2007, we recorded \$70.7 million in acquired in-process research and development projects that had not yet reached technological feasibility and had no future alternative use in connection with the FoxHollow acquisition. The majority of the in-process research and development projects acquired related to in-process projects for RockHawk, Support Catheter, next generation SilverHawk and next generation Rinspirator.

A summary of the fair values assigned to each in-process project at the acquisition date and the estimated total cost to complete each project as of December 31, 2007 is presented below:

Development Projects	Assigned Fair Value	Estimated Total Cost to Complete
SilverHawk	\$51,200	\$ 7,300
RockHawk	13,700	3,400
Support Catheter	2,900	2,300
Rinspirator	2,900	4,500
Estimated fair value of acquired in-process research and development	<u>\$70,700</u>	\$17,500

Tangible assets acquired, net of liabilities assumed, were stated at fair value at the date of the acquisition based on management's assessment or third party appraisals and include a \$1.8 million inventory step-up

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

which was fully amortized at December 31, 2007. The amortization for the inventory step-up is included in product cost of goods sold in the consolidated statement of operations for the year ended December 31, 2007 as the acquired inventory was sold subsequent to the merger.

None of the goodwill resulting from this acquisition is deductible for tax purposes.

## Pro Forma Results of Operations

The unaudited pro forma combined consolidated statement of operations for the years ended December 31, 2007 and 2006 combines the historical results of ev3 and the unaudited pro forma combined results of FoxHollow for the years ended December 31, 2007 and 2006 and gives effect to the acquisition as if it occurred on January 1, 2007 and 2006. FoxHollow's unaudited pro forma combined consolidated statement of operations for the year ended December 31, 2006 gives effect to FoxHollow's September 2006 acquisition of Kerberos Proximal Solutions, Inc., or Kerberos, as if it had occurred on January 1, 2006. Pro forma adjustments have been made related to amortization of identified intangible assets. Pro forma net earnings for 2007 include the \$70.7 million IPR&D charge that was a direct result of the acquisition. The pro forma consolidated results do not purport to be indicative of results that would have occurred had the acquisition been in effect for the periods presented, nor do they claim to be indicative of the results that will be obtained in the future, and do not include any adjustments for cost savings or other synergies. The above pro forma financial results include the results of continuing operations of FoxHollow in its entirety during these periods.

The following table contains unaudited pro forma results (in thousands except per share data) for the years ended December 31, 2007 and December 31, 2006, as if the acquisition had occurred at January 1, 2006:

	Year Ended December 31,							
	2007			2006				
	Re	eported	Pro	Forma	Re	eported	Pro	Forma
Net revenues	\$ 2	284,183	\$ 4	139,893	\$2	02,438	\$3	97,221
Net income (loss)	\$(1	65,744)	\$(2	202,337)	\$(	52,371)	\$(	95,059)
Net income (loss) per share:								
Basic and diluted	\$	(2.37)	\$	(1.98)	\$	(0.93)	\$	(1.01)

## MTI Step Acquisition

On January 6, 2006, we completed the acquisition of the outstanding shares of MTI that we did not already own through the merger of MII with and into MTI, with MTI continuing as the surviving corporation and a wholly owned subsidiary of ev3 Inc. As a result of the merger, each share of common stock of MTI outstanding at the effective time of the merger was automatically converted into the right to receive 0.476289 of a share of our common stock (the "Exchange Ratio") and cash in lieu of any fractional share of our common stock. We issued approximately 7.0 million new shares of our common stock to MTI's public stockholders in the merger. Fair value of the shares issued was measured as the average closing price per share of our stock on the NASDAQ National Market System for the five day trading period centered around the date that the terms of the acquisition were agreed to and announced. In addition, each outstanding option to purchase shares of MTI common stock was converted into an option to purchase shares of our common stock on the same terms and conditions (including vesting) as were applicable under such MTI option. The exercise price and number of shares for which each such MTI option is (or will become) exercisable was adjusted based on the Exchange Ratio. The fair value of the replacement stock options was estimated at the closing date. The unvested portion of the replacement stock options will be recognized as compensation expense over the remaining service period.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS -- (Continued)

The investment was accounted for using the step acquisition method prescribed by ARB 51, Consolidated Financial Statements. Step acquisition accounting requires the allocation of the excess purchase price to the fair value of net assets acquired. The excess purchase price is determined as the difference between the cash paid and the historical book value of the interest in net assets acquired. The effects of the acquisition do not materially change our results of operations. Therefore, pro forma disclosures are not included.

The following table presents the purchase price for the acquisition (in thousands) on the acquisition date of January 6, 2006:

	January 6, 2006
Fair value of shares/options issued	\$ 95,438
Interest acquired in historical book value of MTI	(12,850)
Excess purchase price over historical book values	<u>\$ 82,588</u>

The following summarizes the allocation of the excess purchase price over historical book values (in thousands) arising from the acquisition:

	January 6, 2006
Inventory	
Developed technology	15,548
Customer relationships	9,964
Trademarks and tradenames	
Acquired in-process research and development	1,786
Goodwill	
Accrued liabilities	
Total	

The weighted average life of the acquired intangibles, excluding goodwill, was seven years. The acquired in-process research and development charge was estimated considering an appraisal and represents the estimated fair value of the in-process projects at the date of acquisition of the MTI shares. As of the acquisition date, the in-process projects had not yet reached technological feasibility and had no alternative use. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval to market the products. Accordingly, the value attributable to these projects, which had yet to obtain regulatory approval, was expensed in conjunction with the acquisition. If the projects are not successful, or completed in a timely manner, we may not realize the financial benefits expected from these projects.

The income approach was used to determine the fair value of the acquired in-process research and development. This approach establishes fair value by estimating the after-tax cash flows attributable to any in-process project over its useful life and then discounting these after-tax cash flows back to the present value. The costs to complete each project were based on estimated direct project expenses as well as the remaining labor hours and related overhead costs. In arriving at the value of acquired in-process research and development projects, we considered the project's stage of completion, the complexity of the work to be completed, the costs already incurred, the remaining costs to complete the project, the contribution of core technologies, the expected introduction date and the estimated useful life of the technology. The discount rate used to arrive at the present value of acquired in-process research and development as of the acquisition date was based on the time value of money and medical technology investment risk factors. The discount rate used was approximately 14%. We believe that the estimated acquired in-process research and development amount

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

determined represents the fair value at the date of acquisition and does not exceed the amount a third party would pay for the project.

Prior to acquiring the outstanding shares of MTI that we did not already own on January 6, 2006, we, through our wholly owned subsidiary, MII, acquired a controlling interest in MTI in various step investments commencing in 2001. MTI was a publicly held Delaware corporation that develops, manufactures and markets minimally invasive medical devices for diagnosis and treatment primarily of neurovascular diseases. We held an approximate interest in MTI of 70.0% and 66.0% at December 31, 2005 and 2004, respectively.

We made an additional investment in MTI in 2005. The investment was accounted for using the step acquisition method prescribed by ARB 51, Consolidated Financial Statements. Step acquisition accounting requires the allocation of the excess purchase price to the fair value of net assets acquired. The excess purchase price is determined as the difference between the cash paid and the historical book value of the interest in net assets acquired.

On May 26, 2005, all of the shares of MTI's common stock directly held by Warburg Pincus and Vertical were contributed to ev3 LLC in exchange for 10,804,500 and 3,004,332 common membership units (pre-split basis), respectively. These common membership units were subsequently converted into shares of our common stock in connection with the subsequent merger of ev3 LLC with and into ev3 Inc. on June 21, 2005. MTI shares contributed by Warburg Pincus, representing a 15.7% interest in MTI, have been accounted for as a transfer of assets between entities under common control and the consolidated financial statements give effect to the contribution by Warburg Pincus as though such contributions occurred in 2003 and 2004 when Warburg Pincus acquired its interest in MTI. Shares of MTI contributed by Vertical, representing a 4.3% interest, have been accounted for under the purchase method of accounting at the date of the contribution by Vertical.

The number of membership units of ev3 LLC issued in exchange for the MTI shares directly held by Warburg Pincus and Vertical was determined based on fair value. Fair value of the MTI shares contributed was measured as the average closing price per share of MTI's common stock on the NASDAQ National Market System for the 20 trading days from and including the date our registration statement with respect to our initial public offering was first filed with the Securities and Exchange Commission. Fair value of ev3 LLC's equity issued in exchange for the MTI shares was based on the midpoint of the range of estimated initial public offering prices per share, after consideration of the reverse stock split.

The following table presents the purchase price (in thousands) for the additional investment in 2005:

	May 26, 2005
Fair value of shares issued	\$ 8,404
Cash paid	_
Interest acquired in historical book value of MTI	
Excess purchase price over historical book values	<u>\$ 6,383</u>

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following summarizes the allocation of the excess purchase price over historical book values (in thousands) arising from the additional investment:

	May 26, 2005
Inventory	\$ 104
Developed technology	2,043
Customer relationships	894
Trademarks and tradenames	458
Acquired in-process research and development	868
Goodwill	2,066
Accrued liabilities	(50)
Total	\$6,383

The weighted average life of the acquired intangible assets was five years in each of the allocation periods above. The acquired in-process research and development charge was estimated considering an appraisal and represents the estimated fair value of the in-process projects at the date of contribution of the MTI shares. As of the acquisition date, the in-process projects had not yet reached technological feasibility and had no alternative use. The primary basis for determining technological feasibility of these projects is obtaining regulatory approval to market the products. Accordingly, the value attributable to these projects, which had yet to obtain regulatory approval, was expensed in conjunction with the acquisition. If the projects are not successful, or completed in a timely manner, we may not realize the financial benefits expected from these projects.

To the extent that investments in MTI by third party investors reduced our ownership interest, the difference between the carrying value of the interest indirectly sold by us, and the consideration paid by the third party investor is considered a change in interest transaction. We have adopted an accounting policy of recording change of interest gains or losses within equity as part of comprehensive income (loss) as permitted by Staff Accounting Bulletin ("SAB") 5H. Change of interest gains recorded in equity was \$583,000 for the year ended December 31, 2005.

In 2005, we incurred \$1.9 million of acquisition related costs associated with the purchase of the outstanding shares of MTI that we did not already own.

## 5. Restructuring

In conjunction with the acquisition of FoxHollow, our management began to assess and formulate a plan to restructure certain activities of FoxHollow and to terminate certain contractual agreements assumed in the acquisition of FoxHollow. A significant portion of these costs are related to management's plan to reduce the workforce and include costs for severance and change of control provisions provided for under certain FoxHollow employment contracts. We have reduced the FoxHollow workforce by approximately 130 during the fourth quarter 2007 and we plan to substantially complete the reductions by the fourth quarter 2008. The unpaid portion of these costs are included in accrued compensation and benefits as of December 31, 2007. We will continue to assess multiple functions to finalize our efforts to rationalize the acquired workforce and we estimate we will substantially complete finalization of that plan by the end of the first quarter of 2008. In addition, we have incurred lease termination costs in conjunction with our plan to consolidate our operations. The unpaid portion of these costs are included in accrued liabilities as of December 31, 2007. Provisions with respect to the restructuring activities of FoxHollow are recognized under EITF 95-3, "Recognition of Liabilities in Connection with a Purchase Business Combination", and have been included as a purchase price

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

adjustment within the opening balance sheet. For additional discussion of the purchase price allocation see Note 4.

As part of our restructuring plan, we have also incurred costs related to workforce reductions of the ev3 legacy workforce of approximately 40 in the fourth quarter 2007. The majority of our restructure costs were accounted for under EITF 95-3, the portion related to ev3 legacy workforce were accounted for under FASB Statement 112, "Employers' Accounting for Postemployment Benefits" and recognized in the fourth quarter of 2007 when the amounts became probable and estimable. The unpaid portion of these costs are included in accrued compensation and benefits as of December 31, 2007.

The following table represents a summary of activity (in thousands) associated with the FoxHollow and ev3 legacy restructuring program that occurred from the date of acquisition through December 31, 2007:

	Purchase Price Adjustments (EITF 95-3)	ev3 Legacy Expensed (FAS 112)	Total Restructuring Costs	Amounts Paid	Balance at December 31, 2007
Workforce reductions	\$10,004	\$1,424	\$11,428	\$(2,824)	\$ 8,604
Termination of contractual commitments	2,476		2,476		2,476
Total	<u>\$12,480</u>	<u>\$1,424</u>	<u>\$13,904</u>	<u>\$(2,824)</u>	\$11,080

#### 6. Short-term Investments

Short-term investments consist of debt securities, which have investment grade credit ratings. The debt securities are classified and accounted for as available-for-sale and are reported at fair value with unrealized gains and losses, if any, excluded from earnings and reported in other comprehensive income. Management determines the appropriate classification of its investments in securities at the time of purchase and reevaluates such determination at each balance sheet date. Our short-term investments consist of U.S. Government securities as well as floating rate taxable municipal and corporate bonds with maturities from 2019 to 2036. We have the option to put the bonds to the remarketing agent who is obligated to repurchase the bonds at par. As of December 31, 2007 and 2006, our cost approximated fair value related to these investments.

## 7. Inventories

Inventory consists of the following (in thousands):

	December 31,		
	2007	2006	
Raw materials	\$ 18,003	\$ 7,100	
Work-in-progress	3,946	3,271	
Finished goods	53,063	36,478	
	75,012	46,849	
Inventory reserve	(10,968)	(4,725)	
Inventory, net	\$ 64,044	\$42,124	

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

# 8. Property and Equipment

Property and equipment consists of the following (in thousands):

•	December 31,		
	2007	2006	
Machinery and equipment	\$ 27,405	\$ 20,472	
Office furniture and equipment	16,897	11,440	
Leasehold improvements	14,656	9,750	
Construction in progress	6,957	2,040	
	65,915	43,702	
Less:			
Accumulated depreciation and amortization	(27,930)	(19,630)	
Property and equipment, net	<u>\$ 37,985</u>	<u>\$ 24,072</u>	

Depreciation and amortization expense for property and equipment for the years ended December 31, 2007, 2006 and 2005 was \$8.4 million, \$5.6 million and \$4.1 million, respectively.

# 9. Goodwill and Other Intangible Assets

The changes in the carrying amount of goodwill by operating segment for the years ended December 31, 2007 and 2006 were as follows (in thousands):

	Peripheral Vascular	Neuro- vascular	Total
Balance as of January 1, 2006	\$ 71,307	\$23,149	\$ 94,456
Goodwill related to acquisition of MTI common stock		54,605	54,605
Balance as of December 31, 2006	71,307	77,754	149,061
Contingent consideration related to acquisition milestone		7,500	7,500
Goodwill related to acquisition of FoxHollow	430,087		430,087
Balance as of December 31, 2007	\$501,394	\$85,254	\$586,648

ev3 Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Other intangible assets consist of the following (dollars in thousands):

		December 31,					
	Weighted		2007			2006	
	Average Useful Life (in years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents and licenses	5.0	\$ 13,802	\$ (4,890)	\$ 8,912	\$11,435	\$ (4,009)	\$ 7,426
Developed technology	10.0	202,416	(50,213)	152,203	63,616	(40,119)	23,497
Trademarks and tradenames	9.0	12,222	(3,454)	8,768	5,122	(2,634)	2,488
Customer relationships	10.0	56,094	(13,094)	43,000	16,094	(9,491)	6,603
Distribution rights	2.5	9,274	(3,710)	5,564	_	_	<del></del> .
Merck exclusivity	3.3	13,600	(1,047)	12,553			
Other intangible assets		\$307,408	<u>\$(76,408)</u>	\$231,000	<u>\$96,267</u>	<u>\$(56,253)</u>	\$40,014

Intangible assets are amortized using methods which approximate the benefit provided by the utilization of the assets. Patents and licenses, developed technology and trademarks and tradenames are amortized on a straight line basis. Customer relationships are amortized using both straight-line and accelerated methods that approximate the pattern of economic benefit.

Total amortization of intangible assets was \$20.3 million, \$17.2 million and \$10.7 million for the years ended December 31, 2007, 2006 and 2005, respectively.

Based on the intangible assets in service as of December 31, 2007, estimated amortization expense for the next five years ending December 31 is as follows (in thousands):

2008	 	\$31,290
2009	 	26,704
2010		
2011	 ·	18,104
2012	 	18,047

## 10. Investments

We had a licensing agreement and an approximate 14% interest in Genyx Medical, Inc. ("Genyx"). The carrying value of our investment in Genyx was fully written off and reduced to zero as of December 31, 2004, and we had no obligation to fund Genyx's operations. In January 2005, we sold our interest in Genyx and recorded a gain of \$3.7 million. During the second quarter 2006, we received a milestone payment of \$153,000 related to the sale of our investment in Genyx. During the second quarter 2005, we received an \$878,000 milestone payment related to the 2002 sale of our investment in Enteric. These amounts are included in the "Gain on sale of investments, net" caption in the Other Income/Expense section of our statements of operations.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 11. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

,	December 31	
	2007	2006
Accrued professional services	\$ 3,016	\$ 1,900
Accrued clinical studies	1,814	359
Accrued litigation	16,054	1,301
Dendron earn-out payment	7,500	_
Tax liabilities	1,491	1,152
Accrued royalties	2,062	845
Deferred rent	2,368	409
Accrued other	15,124	4,136
Total accrued liabilities		\$10,102

## 12. Long-Term Debt

Long-term debt consists of the following (in thousands):

	December 31,	
	2007	2006
Equipment term loan	\$10,000	\$ 7,500
Less: current portion		
Total long-term debt	\$ 6,429	<u>\$ 5,357</u>

On June 28, 2006, our operating subsidiaries, ev3 Endovascular, Inc., ev3 International, Inc. and Micro Therapeutics, Inc., entered into a Loan and Security Agreement, with Silicon Valley Bank, or SVB, consisting of a two-year \$30.0 million revolving line of credit and a 48-month \$7.5 million equipment financing advance ("Equipment Advance A"). On March 15, 2007, we entered into an amendment to our existing Loan Agreement with SVB. The amendment added an additional \$5 million of equipment financing ("Equipment Advance B"), increasing the total available equipment advances to \$12.5 million. Borrowings under the revolving line bear interest at a variable rate equal to SVB's prime rate. Borrowings under the equipment advances bear interest at a variable rate per annum equal to SVB's prime rate plus 1.0%. The prime rate at December 31, 2007 was 7.25%. Accrued interest on any outstanding balance under the revolving line and the equipment financing advances is payable monthly in arrears. Amounts that were outstanding under the Equipment Advance A as of December 31, 2006 are payable in 42 consecutive equal monthly installments of principal, beginning on January 31, 2007. Amounts that were outstanding under the Equipment Advance B are payable in 42 equal monthly payments of principal, commencing on the last day of the seventh month following the date that the Equipment Advance B was made and continuing on the last day of each month thereafter until the last day of the 48th month following the date of such advance. As of December 31, 2007, we had \$5.4 million in outstanding borrowings under the Equipment Advance A and \$4.6 million in outstanding borrowings under the Equipment Advance B and no outstanding borrowings under the revolving line of credit; however, we had approximately \$2.4 million of outstanding letters of credit issued by SVB, which reduces the maximum amount available under our revolving line of credit to approximately \$27.6 million.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Annual maturities of our long-term debt at December 31, 2007 are as follows (in thousands):

2008	\$ 3,571
2009	3,571
2010	2,500
2011	358
Total	\$10,000

## Endovascular Notes Payable

Endovascular issued demand notes to Warburg Pincus and Vertical in order to obtain the necessary funds to complete acquisitions, meet working capital requirements and fund operating losses prior to the company's initial public offering. At June 21, 2005, the closing date of our initial public offering, Endovascular had outstanding \$316.0 million aggregate principal amount of demand notes plus \$44.7 million of accrued and unpaid interest thereon. These notes were payable to Warburg Pincus, our largest stockholder, and Vertical, our then second largest stockholder. Immediately prior to our initial public offering, we issued 21,964,815 and 1,194,489 shares of common stock to Warburg Pincus and Vertical, respectively, in exchange for their contribution of \$324.2 million principal amount of the demand notes and a portion of the accrued and unpaid interest thereon. Upon successful consummation of our initial public offering, we utilized \$36.5 million of the net proceeds to reduce our financing balance to zero at June 21, 2005. The notes provided for interest at 8% per annum and interest expense totaled \$12.2 million for the year ended December 31, 2005.

## 13. Gain (Loss) on Sale of Assets

On June 15, 2007, we entered into an Intellectual Property Transfer Agreement with Atritech, Inc. pursuant to which we sold and licensed, on a royalty-free perpetual basis, certain intellectual property relating to percutaneously delivered implants within the left atrial appendage for prevention of emboli migration out of the appendage. In exchange for the assets and license, we received \$2.0 million in cash, shares of Atritech common stock representing approximately 8% of the equity of Atritech on a fully diluted basis and an unsecured, subordinated, non-interest-bearing promissory note in the principal amount of \$5.6 million, the unpaid principal balance of which will become immediately due and payable only upon an initial public offering by Atritech or a sale transaction, in each case resulting in gross proceeds of less than a certain amount. During 2007, we recognized a gain of \$1.0 million representing the amount of the \$2.0 million cash payment received in excess of the net book value of the assets sold to Atritech. In accordance with Staff Accounting Bulletin Topic 5U: "Miscellaneous Accounting — Gain Recognition on the Sale of a Business or Operating Assets to a Highly Leveraged Entity," we have deferred the potential gain related to the equity and debt consideration received and the deferred gain will be recognized when it becomes realized or probable of realization.

## 14. Interest (Income) / Expense

Interest income and interest expense for the years ended December 31, 2007, 2006 and 2005 are as follows (in thousands):

	2007_	2006	2005
Interest income	\$(3,284)	\$(2,469)	\$ (2,475)
Interest expense	1,374	774	12,391
Interest (income) / expense	<u>\$(1,910)</u>	<u>\$(1,695</u> )	\$ 9,916

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

# 15. Members' Equity and Redeemable Convertible Preferred Membership Units

ev3 LLC, when it was formed, authorized and issued 733,455 Common Membership Units (Common), 24,040,718 Class A Preferred Membership Units (Class A) and 41,077,336 Class B Preferred Membership Units (Class B). The Class A units were issued in exchange for 100% of the outstanding units of MII, and the Class B units and Common units were exchanged for 100% of the outstanding preferred and common shares of Endovascular. This exchange has been reflected retroactively in the consolidated financial statements.

## Redeemable Convertible Preferred Membership Units

Class A and Class B Preferred units (together the "Preferred units") were redeemable at the option of the holder. Preferred units had special rights relating to conversion to Common units, liquidation, election of directors, and certain other matters. The Preferred units were entitled to vote on all matters along with the holders of Common units on an as-if converted basis. The Preferred units were convertible into Common units on a 1:6 basis, subject to an adjustment for any interest, splits, distribution, or other actions.

In connection with the merger of ev3 LLC with and into ev3 Inc. in 2005, 24,040,718 Class A preferred membership units of ev3 LLC with a carrying value of \$98.7 million and 41,077,336 Class B preferred membership units of ev3 LLC with a carrying value of \$167.4 million were converted into common membership units of ev3 LLC, and subsequently into shares of our common stock, on a 1:1 basis. The newly converted shares were then subject to a 1-for-6 reverse stock split (See Note 1).

The preferred units were accreted to their liquidation value at the first redemption date with the accretion in the value of the preferred units recorded as a charge to the accumulated deficit until the date of conversion in common equity in 2005.

## 16. Equity Based Compensation Plans

We have several stock-based compensation plans under which stock options and other equity incentive awards have been granted. Under the ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan, eligible employees, outside directors and consultants may be awarded options, stock grants, stock units or stock appreciation rights. The terms and conditions of an option, stock grant, stock unit or stock appreciation right (including any vesting or forfeiture conditions) are set forth in the certificate evidencing the grant. Subject to adjustment as provided in the plan, 11.3 million shares of our common stock are authorized for issuance under the plan, including 3.3 million shares that were unallocated and available for grant under stock plans assumed by ev3 in connection with our acquisition of FoxHollow and under the terms of the 2005 plan became available for issuance under the 2005 plan. As of December 31, 2007, 6.2 million shares of our common stock had been issued under the 2005 plan or were subject to outstanding awards granted under the 2005 plan and 5.1 million shares remained available for future grants.

Options, other than those granted to outside consultants, generally vest over a four-year period and expire within a period of not more than ten years from the date of grant. Vested options generally expire 90 days after termination of employment. Options granted to outside consultants generally vest over the term of their consulting contract and generally expire 90 days after termination of the consulting relationship. The exercise price per share for each option is set by the board of directors or the compensation committee at the time of grant and pursuant to the terms of the plan may not be less than the fair market value per share on the grant date.

Upon consummation of our initial public offering, the ev3 LLC 2003 Incentive Plan was terminated with respect to options available for grant that were not granted prior to the offering. Prior to our January 6, 2006 acquisition of the remaining outstanding shares of MTI that we did not already own, MTI had a 1993 Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan and a 1996 Stock Incentive Plan. As a result of the merger of MII with and into MTI, the outstanding options issued under these

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

MTI plans were converted into options to purchase an aggregate of 2,449,905 shares of our common stock. MTI also had an Employee Stock Purchase Plan, which was terminated effective December 31, 2005 (see Note 4). As of December 31, 2007, 2.2 million shares of our common stock were issuable pursuant to outstanding stock options and other awards granted under the ev3 LLC plan and the MTI stock plans.

As a result of our acquisition of FoxHollow, all outstanding options to purchase shares of FoxHollow common stock and other equity awards based on FoxHollow common stock, which were outstanding immediately prior to the effective time of the acquisition and whether or not then exercisable or vested, were converted into and became, respectively, options to purchase shares of our common stock and with respect to all other FoxHollow equity awards, awards based on shares of our common stock, in each case, on terms substantially identical to those in effect prior to the effective time of the acquisition, except for adjustments to the underlying number of shares and the exercise price based on an exchange ratio reflected in the acquisition consideration and other adjustments as provided in the merger agreement. As a result of the transaction, we assumed the FoxHollow Technologies, Inc. 2004 Equity Incentive Plan and the FoxHollow Technologies, Inc. 1997 Stock Plan and each outstanding converted option and other stock-based award. Certain FoxHollow employees had change of control agreements such that 50% of unvested options became vested at the time of the acquisition. The remaining 50% would vest either at time of involuntary termination or within one year from the date of the acquisition.

In addition to our 2005 Incentive Stock Plan, we maintain the ev3 Inc. Employee Stock Purchase Plan ("ESPP"). The maximum number of shares of our common stock available for issuance under the ESPP is 750,000 shares, subject to adjustment as provided in the ESPP. The ESPP provides for six-month offering periods beginning on January 1 and July 1 of each year. The first offering period commenced on January 1, 2007. The purchase price of the shares is 85% of the lower of the fair market value of our common stock at the beginning or end of the offering period. This discount does not exceed the maximum discount rate permitted for plans of this type under Section 423 of the Internal Revenue Code of 1986, as amended. The ESPP is compensatory for financial reporting purposes.

A summary of option activity for all plans (dollars in thousands, except per share amounts) during the year ended December 31, 2007 is as follows:

	Awarded Shares Outstanding	Weighted- Average Exercise Price per Share	Aggregate Intrinsic Value
Balance at January 1, 2007	5,359,248	\$12.47	\$26,863
FoxHollow options converted to ev3 options as a result of the acquisition	6,351,497	\$15.48	
Options to purchase common stock	2,690,322	\$16.90	
Exercised	(664,178)	\$10.13	
Forfeited	(1,434,019)	\$15.50	
Expired	(251,309)	\$18.81	
Balance at December 31, 2007	12,051,561	<u>\$14.68</u>	<u>\$10,981</u>
Options exercisable at December 31, 2007	6,478,366	\$13.83	\$ 9,761

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

A summary of the weighted average grant date fair value of options granted under all plans for each period is as follows:

•	Year Ended December 31,				
	2007 ev3 Inc.	2006	2006 200		
		ev3 Inc.	ev3 Inc.	MTI	
Weighted average grant date fair value of options issued:					
At market	\$6.55	\$7.11	\$6.05	\$1.95	
Below market	\$ —	\$ —	\$5.05	\$1.86	

As of December 31, 2007, the total compensation cost for nonvested options not yet recognized in our statements of operations was \$33.9 million, net of estimated forfeitures. This amount is expected to be recognized over a weighted average period of 2.9 years.

The intrinsic value of a stock option award is the amount by which the fair market value of the underlying stock exceeds the exercise price of the award. The total intrinsic value of options exercised was \$4.8 million and \$9.1 million during the years ended December 31, 2007 and 2006, respectively.

For options outstanding and exercisable at December 31, 2007, the exercise price ranges and average remaining lives were as follows:

		<b>Options Outstand</b>	Options Exercisable		
Exercise Price per Share	Number Outstanding	Weighted- Average per Share Exercise Price	Weighted- Average Remaining Contractual Life	Number Exercisable	Weighted- Average Exercise Price per Share
\$ 0.20 - \$12.71	2,368,193	\$ 8.07	6.0 years	2,035,961	\$ 7.92
\$12.90 - \$14.00	3,460,267	\$13.39	8.6 years	1,844,237	\$13.38
\$14.23 - \$16.75	2,722,059	\$16.11	9.0 years	695,914	\$15.84
\$16.78 - \$18.76	2,270,761	\$17.59	8.3 years	1,020,642	\$17.50
\$18.91 - \$96.06	1,230,281	\$22.44	7.4 years	881,612	\$22.57
	12,051,561	\$14.68	8.0 years	6,478,366	\$13.83

A summary of restricted stock awards activity for all plans (dollars in thousands, except per share amounts) during the year ended December 31, 2007 is as follows:

	Awarded Shares Outstanding	Weighted-Average Grant Date Fair Value
Nonvested balance at January 1, 2007	217,774	\$15.42
FoxHollow restricted stock awards converted to ev3 awards as a result of the acquisition	254,166	\$16.64
Granted:		
Restricted stock awards	1,302,299	\$17.00
Vested	(282,138)	\$16.72
Forfeited	(199,136)	\$16.88
Nonvested balance at December 31, 2007	1,292,965	<u>\$16.73</u>

The value of these shares of restricted stock was measured at the closing market price of our common stock on the grant date. The unamortized compensation expense for these awards was \$23.7 million as of

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

December 31, 2007, which will be recognized over the remaining weighted average vesting period of approximately 3.5 years.

During 2000 and 2001, Warburg Pincus and certain of our employees and directors entered into loan agreements in order for certain employees and directors to buy ownership interests in us. These outstanding loans are considered to be a part of a stock compensation arrangement. Modifications are measured for compensation expense. Additional compensation expense, if any, is recognized over the remaining life of the loan and is immaterial for the years ended December 31, 2007, 2006 and 2005. The total outstanding principal balance and accrued interest on the notes held by Warburg Pincus and issued to certain of our employees and directors at December 31, 2007 and 2006 was an aggregate of \$5.2 million and \$4.9 million, respectively.

#### 17. Defined Contribution Plans

We offer substantially all our employees the opportunity to participate in defined contribution retirement plans qualifying under the provisions of Section 401(k) of the Internal Revenue Code. The general purpose of these plans is to provide employees with an incentive to make regular savings in order to provide additional financial security during retirement. The plans provide for a match of 50% of the employees' pre-tax contribution, up to a maximum of 3% of eligible earnings. The employee is immediately vested in the matching contribution. Compensation expense related to this plan was \$2.4 million, \$2.1 million and \$1.3 million for the years ended December 31, 2007, 2006 and 2005, respectively. Expenses to administer the plans are borne by the Company and have amounted to approximately \$11,000, \$12,000 and \$13,000 for the years ended 2007, 2006 and 2005, respectively.

## 18. Income Taxes

Following is a reconciliation of the U.S. Federal statutory rate to our effective tax rate:

	For the Years Ended December 3		
	2007	2006	2005
U.S. Federal statutory tax rate	(35.0)%	(35.0)%	(34.0)%
Change in valuation allowance	20.2%	39.6%	35.9%
Acquired in-process research and development	15.1%	1.2%	0.3%
Foreign income taxes	0.6%	0.9%	3.1%
Meals and entertainment	0.3%	0.6%	0.3%
State income taxes	(0.1)%	(3.0)%	(5.4)%
Other, net	(0.5)%	(3.0)%	<u>0.5</u> %
Effective tax rate	0.6%	<u>1.3</u> %	<u>0.7</u> %

The components of our provision for income taxes are as follows (in thousands):

		he Years E ecember 3	
	2007	2006	2005
Current:			
U.S	\$ —	<b>\$</b> —	\$ <del></del>
Foreign	949	688	525
Total Current	949	688	525
Deferred:	_=		
Total tax provision	<u>\$949</u>	\$688	<u>\$525</u>

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

We had the following deferred tax assets and liabilities as of (in thousands):

	Decemb	er 31,
	- 2007	2006
Deferred Tax Assets:	•	
Net operating loss carryforwards	\$ 214,569	\$ 170,428
Capitalized research & development costs	24,477	16,588
Other reserves and accruals	12,145	2,792
Inventories	8,840	1,794
Tax credit carryforwards	4,180	5,182
Deferred revenue	3,593	
Unrealized losses on investments	3,177	3,135
Property and equipment	3,046	709
Other	5,184	3,095
Valuation allowance	(199,040)	<u>(191,960</u> )
Total deferred tax assets	\$ 80,171	<u>\$ 11,763</u>
Deferred Tax Liabilities:		
Intangible assets	(80,171)	(11,763)
Net deferred tax asset (liability)	<u> </u>	<u> </u>

We have established a complete valuation allowance against our net deferred tax assets because it was determined by management at both December 31, 2007 and 2006 that it was more likely than not that such deferred tax assets would not be realized.

In December 2007, the FASB issued SFAS No. 141R, Business Combinations (SFAS 141R). SFAS 141R is effective for us beginning in 2009. It is estimated that \$22.3 million of the net valuation allowance balance relates to activity of acquired entities which was generated prior to their acquisition by ev3 Inc. If such amounts are released prior to the adoption of SFAS 141R, the reversal of valuation allowance will affect goodwill. If such amounts reverse subsequent to the adoption of SFAS 141R, such reversals will favorably impact the income tax provision in the period of reversal. We are still assessing the full impact of this standard on our future consolidated financial statements.

We adopted the provisions of FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, on January 1, 2007. As a result of the implementation of Interpretation 48, we recognized approximately a \$717,000 increase in the liability for unrecognized tax benefits, which was accounted for as an increase to the January 1, 2007, balance of accumulated deficit.

A reconciliation of the beginning and ending balances of the total amounts of gross unrecognized tax benefits is as follows (in thousands):

Gross unrecognized tax benefits at January 1, 2007	\$4,656
Current year acquisition	
Increase for tax positions in prior years	1,648
Decrease for tax positions in prior years	
Settlements	(163)
Increase for tax positions in current years	<u>870</u>
Gross unrecognized tax benefits at December 31, 2007	\$9,430

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The total amount of net unrecognized tax benefits that, if recognized, would affect the effective tax rate was \$734,000 at December 31, 2007. We accrue interest and penalties related to unrecognized tax benefits in our provision for income taxes. At December 31, 2007, we had accrued interest and penalties related to unrecognized tax benefits of \$32,000 and \$240,000, respectively.

Management believes that it is reasonably possible that the total amounts of unrecognized tax benefits will decrease between zero and \$435,000 due to the potential resolution of the tax examinations in foreign jurisdictions and federal expiration of credit carryforwards within the 12 months subsequent to December 31, 2007.

We or one of our subsidiaries file income tax returns in the U.S. federal jurisdiction and in various U.S. state and foreign jurisdictions. With few exceptions, as a result of net operating loss carryforwards generated we are subject to U.S. federal and state income tax examinations by tax authorities for years after 1993, and for years after 2002 in foreign jurisdictions.

At December 31, 2007, we had U.S. net operating loss carryforwards of \$532.1 million (net of \$35.6 million expected to expire before utilization due to the Internal Revenue Code ("IRC") Section 382 limitation) and foreign net operating loss carryforwards of \$47.4 million (net of uncertain tax positions recorded pursuant to FIN 48). The general time frame of the net operating loss carryforwards expiration is as follows (in thousands):

U.S.	Foreign	Total	Carryforward Expiration Period
\$ 27,060	\$17,358	. \$ 44,418	2008 - 2018 ,
122,798	_	. 122,798	2019 - 2022
382,270	<del></del> :	382,270	2023 - 2027
	30,005	30,005	No expiration date
\$532,128	<u>\$47,363</u>	\$579,491	$(x_i, y_i) = (x_i, y_i)$

In addition, we currently have approximately \$338.0 million in state net operating loss carryforwards. These net operating loss carryforwards will expire in varying amounts between 2008 and 2027.

We have research and experimentation credit carryforwards for federal and California purposes of approximately \$2.4 million and \$2.4 million, respectively (collectively net of \$1.1 million expected to expire before utilization due to the IRC Section 382 limitation and net of uncertain tax positions recorded pursuant to FIN 48) which will expire between 2008 and 2022. We also have a manufacturer's investment credit carryforward for California tax reporting purposes of approximately \$145,000 (net of \$20,000 limited under California law and net of uncertain tax positions recorded pursuant to FIN 48) which will expire between 2008 and 2012.

The acquisition of FoxHollow in October 2007, and the acquisitions made during 2001 and 2002, resulted in ownership changes which limit our ability to utilize our net operating loss and credit carryforwards pursuant to IRC Section 382. Additionally, a number of our subsidiaries have more than one IRC Section 382 limitation associated with their NOL carryovers as a result of multiple past ownership changes. Subsequent changes in equity could further limit the utilization of the federal and state net operating loss and credit carryforwards. Such limitations could result in expiration of carryforward periods prior to utilization of the net operating loss and credit carryforwards. The net operating losses of certain subsidiaries acquired in prior years are subject to the separate return limitation year ("SRLY") provisions of the Treasury Regulations. Net operating loss carryforwards from these acquisitions may only be used to offset future taxable income generated by these subsidiaries.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

As a result of the acquisition with FoxHollow on October 4, 2007, we will include FoxHollow in our consolidated 2007 U.S. tax return. In connection with the purchase accounting related to the acquisition of FoxHollow, deferred tax liabilities were recorded on certain intangible assets arising from the acquisition. This resulted in a decrease to the net deferred asset of the company and thus a reduction of the valuation allowance.

## 19. Commitments and Contingencies

## **Operating Leases**

We lease various manufacturing and office facilities and certain equipment under operating leases.

Total future non-cancelable minimum lease commitments are as follows (in thousands):

#### Years ending December 31:

2008	\$ 6,456
2009	5,764
2010	3,963
2011	2,474
2012	1,435
Thereafter	6,503
	\$26,595

Rent expense related to non-cancelable operating leases for the years ended December 31, 2007, 2006 and 2005 was \$5.1 million, \$4.1 million and \$3.9 million, respectively.

Portions of our payments for operating leases are denominated in foreign currencies and were translated in the table above based on their respective U.S. dollar exchange rates at December 31, 2007. These future payments are subject to foreign currency exchange rate risk.

## Purchase Obligations

We had entered into a supply agreement with Invatec, which included minimum purchase obligations over the initial three-year term beginning January 1, 2005, and were committed to \$32.7 million of minimum inventory purchases for 2007. These payments were denominated in Euros and were translated at the respective exchange rate at December 31, 2007. These future payments were subject to foreign currency exchange rate risk. The agreement could be terminated early by either party upon the occurrence of certain events, including by Invatec upon a change of control of ev3 Inc. involving a competitor of Invatec or if ev3 failed to achieve certain minimum annual purchase requirements. In the event Invatec terminated the agreement upon the occurrence of certain events, including a change of control of ev3 Inc. involving a competitor of Invatec, we could have been required to pay to Invatec liquidated damages of \$5.0 million or \$15.0 million, depending on the event causing the termination. In lieu of terminating the agreement for our failure to meet certain minimum annual purchase requirements, Invatec could have required us to pay an indemnification amount equal to 80% of the difference between the aggregate minimum annual value of purchases required under the agreement and the total actual purchases of products during the same contractual year.

On February 15, 2007, we entered into a termination and settlement agreement with Invatec S.r.l. originally dated June 24, 2004 and further amended effective as of December 31, 2004, pursuant to which the parties mutually agreed to terminate our existing Distribution Agreement (the "Existing Distribution Agreement"). Under the terms of the termination and settlement agreement, we are not obligated to pay Invatec any liquidated damages in connection with the termination of the Existing Distribution Agreement. Also on

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

February 15, 2007, we executed a new distribution agreement with Invatec Technology Center GmbH appointing us as a non-exclusive distributor of certain of Invatec's products for the United States and Puerto Rico (the "Distribution Agreement").

In connection with the execution of the Distribution Agreement, we paid Invatec \$9.3 million for these distribution rights that have been accounted for as an intangible asset and amortized over the term of the agreement. This payment was comprised of a one time sign-up fee of \$6.5 million paid in cash and retainage of the remaining unamortized portion of the recoverable sign-up fee from the Existing Distribution Agreement of \$2.8 million as additional consideration. The net carrying value of the distribution rights was \$5.6 million at December 31, 2007. The Distribution Agreement provides for certain minimum annual purchases by ev3, which are less than the annual purchase requirements under the Existing Distribution Agreement. We met the minimum purchase requirements for 2007. The required minimum purchase requirement for 2008 is \$14.9 million. If we fail to achieve the minimum annual purchase requirements, Invated may require us to pay an amount to Invatec equal to an agreed upon value multiplied by the difference between the portion of minimum annual amount of purchases required under the agreement and the total actual purchases of products by us during the same period. Invated also retained the right to sell its products into the United States under other brands. If Invatec elects to sell certain of its products under its own brand or as co-branded with another party in the United States or Puerto Rico, we will no longer be required to make our minimum annual purchases under the Distribution Agreement, however, Invatec will still be obligated to supply us with product. During the term of the Distribution Agreement, we are permitted to design and develop (but not launch, market, sell, promote or distribute) competing products in the United States and Puerto Rico.

The term of the Distribution Agreement extends until December 31, 2008. The Distribution Agreement may be terminated early by us or Invatec upon the occurrence of certain events, including an uncured breach of the agreement, and by us with six months prior written notice so long as we purchase a prorated portion of our annual minimum purchase amount through the termination date. Invatec will not be able to terminate the Distribution Agreement in the event a competitor of Invatec acquires a controlling interest in us, as was allowed under the Existing Distribution Agreement, so long as such competitor continues to operate ev3 independently or causes ev3 to purchase its annual minimum purchase requirements. Under the Distribution Agreement, we are permitted to continue to sell our inventory of Invatec products for a period of up to six months after the termination of the Distribution Agreement.

## Letters of Credit

As of December 31, 2007, we had \$3.4 million of outstanding letters of credit, which were collateralized by \$1.0 million of restricted cash and \$2.4 million were backed by our revolving line of credit.

# Financed Insurance Policies

In fiscal year 2006 and prior, we routinely entered into agreements to finance insurance premiums for periods not to exceed the terms of the related insurance policies. In the three months ended July 2, 2006, we entered into an agreement to finance \$3.5 million in insurance-related premiums associated with the annual renewal of certain of our insurance policies. The amount financed accrues interest at a 6.4% annual rate and is payable in monthly installments over an 11 month period. During the third quarter 2006, we agreed to pay a portion of the insurance premiums directly to the carrier thereby reducing the amount financed by \$1.4 million. The remaining outstanding balance under these agreements were \$665,000 as of December 31, 2006, and is included in accrued liabilities on our consolidated balance sheet. As of December 31, 2007, there is no outstanding balance under this type of agreement.

## Earn-Out Contingencies

Under the terms of the stock purchase agreement we entered into in connection with our acquisition of Dendron in September 2000, we may be required to make additional payments which are contingent upon

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Dendron products achieving certain revenue targets between 2003 and 2008. In 2003, the \$4.0 million revenue target for sales of Dendron products during 2003 was met. Accordingly, an additional payment to the former Dendron stockholders of \$3.75 million was made in 2004. In 2004, the \$5.0 million revenue target for sales of Dendron products during 2004 was met. Accordingly, a payment to the former Dendron stockholders of \$3.75 million was accrued in 2004 and was paid in 2005. A final payment of \$7.5 million was earned in 2007 as Dendron products achieved annual revenues of \$25 million. Accordingly, a payment to the former Dendron stockholders of \$7.5 million was accrued in 2007 and will be paid in 2008.

# License Agreements

We have various licensing agreements with third parties for the use of certain technologies for which royalties ranging from 1.25% to 7% of net sales are paid. We incurred costs of \$8.1 million, \$2.9 million and \$1.7 million in connection with royalty and licensing agreements, for the years ended December 31, 2007, 2006 and 2005, respectively.

## Contingencies

We are from time to time subject to, and are presently involved in, various pending or threatened legal actions and proceedings, including those that arise in the ordinary course of our business. Such matters are subject to many uncertainties and to outcomes that are not predictable with assurance and that may not be known for extended periods of time. We record a liability in our consolidated financial statements for costs related to claims, including future legal costs, settlements and judgments, where we have assessed that a loss is probable and an amount can be reasonably estimated. Our significant legal proceedings are discussed below. While it is not possible to predict the outcome for most of the legal proceedings discussed below, the costs associated with such proceedings could have a material adverse effect on our consolidated results of operations, financial position or cash flows of a future period.

## Global Coil Patent Litigation

In September 2000, Dendron, which was acquired by MTI in 2002, was named as the defendant in three patent infringement lawsuits brought by The Regents of the University of California, as the plaintiff, in the District Court (Landgericht) in Dusseldorf, Germany. The complaints requested a judgment that Dendron's EDC I coil device infringed three European patents held by the plaintiff and asked for relief in the form of an injunction that would prevent Dendron from producing and selling the devices, as well as an award of damages caused by Dendron's alleged infringement, and other costs, disbursements and attorneys' fees. Dendron instituted challenges to the validity of each of these patents by filing opposition proceedings with the European Patent Office, or EPO, against one of the patents (MTI joined Dendron in this action in connection with its acquisition of Dendron), and by filing nullity proceedings with the German Federal Patents Court 'against the German component of the other two patents. All three appeal proceedings are currently stayed on the basis of the validity challenges brought by Dendron.

Concurrent with MTI's acquisition of Dendron, MTI initiated a series of legal actions related to our Sapphire coils in the Netherlands and the United Kingdom, which included a cross-border action that was heard by a Dutch court, as further described below. The primary purpose of these actions was to assert both invalidity and non-infringement by MTI of certain patents held by others. The range of patents at issue are held by The Regents of the University of California, with Boston Scientific Corporation subsidiaries named as exclusive licensees, collectively referred to as the "patent holders," related to detachable coils and certain delivery catheters.

In December 2003, the University of California filed an action against us in the United States District Court for the Northern District of California alleging infringement by us with respect to a range of patents held by the University of California related to detachable coils and certain delivery systems. We filed a

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

counterclaim against the University of California asserting non-infringement by us, invalidity of the patents and inequitable conduct in the procurement of certain patents. In addition, we filed a claim against the University of California and Boston Scientific Corporation for violation of federal antitrust laws, with the result that the court has subsequently decided to add Boston Scientific as a party to the litigation.

We have reached agreements in principle with The Regent of the University of California and Boston Scientific Corporation to settle on a worldwide basis, the Global Coil Patent Litigation. The terms of the agreements in principle include the following: all claims by all parties will be dismissed; we will continue to be able to self all involved product lines with no future royalty obligation; and we will make a one-time payment of approximately \$11.7 million to the University of California and a one-time payment of approximately \$3.7 million to Boston Scientific. The settlement remains subject to negotiation of final written agreements among the parties and the settlement terms with the University of California remain subject to final approval by The Regents of the University of California. In addition, we have paid approximately \$5.8 million of legal fees and expenses associated with the litigation. As a result of these agreements in principle, the previously assigned trial date of October 16, 2007, with respect to the U.S. case, has been continued indefinitely.

## **Embolic Protection Patent Litigation**

On March 30, 2005, we were served with a complaint by Boston Scientific Corporation and one of its affiliates which claims that some of our products, including our SpideRX Embolic Protection Device, infringe certain of Boston Scientific's patents. This action was brought in the United States District Court for the District of Minnesota. Subsequently, we added counterclaims for infringement of three of our patents; Boston Scientific has added two patents into its claims, as well as a claim against us for misappropriation of trade secrets.

We have reached an agreement in principle with Boston Scientific Corporation to settle the Embolic Protection Patent Litigation. The terms of the agreement include the following: all claims by all parties will be dismissed; we will continue to be able to sell all involved product lines with no future royalty obligation; and we will make a one-time payment of approximately \$3.7 million to Boston Scientific. The settlement is subject to negotiation of final written agreements among the parties. The \$3.7 million one-time payment is included in the \$19.1 million special charge recorded as of December 31, 2007. See additional discussion in the "Global Coil Patent Litigation" section above.

#### Appriva Medical, Inc. Acquisition Litigation

The acquisition agreement relating to our acquisition of Appriva Medical, Inc. contains four milestones to which payments relate. The first milestone was required by its terms to be achieved by January 1, 2005 in order to trigger a payment equal to \$50 million. We have determined that the first milestone was not achieved by January 1, 2005 and that the first milestone is not payable. On May 20, 2005, Michael Lesh, as an individual seller of Appriva stock and purporting to represent certain other sellers of Appriva stock, filed a complaint in the Superior Court of the State of Delaware with individually specified damages aggregating \$70 million and other unspecified damages for several allegations, including that we, along with other defendants, breached the acquisition agreement and an implied covenant of good faith and fair dealing by willfully failing to take the steps necessary to meet the first milestone under the agreement, and thereby also failing to meet certain other milestones, and further that one milestone was actually met. The complaint also alleges fraud, negligent misrepresentation and violation of state securities laws in connection with the negotiation of the acquisition agreement. We believe these allegations are without merit and intend to vigorously defend this action. We filed a motion to dismiss the complaint, which the court granted in June 2006 on standing grounds. The plaintiff filed a petition for re-argument, which was denied on October 31, 2006. On November 29, 2006, the plaintiff appealed the trial court's decision granting our motion to dismiss.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

By decision dated November 1, 2007, the Delaware Supreme Court reversed and remanded the trial court's ruling. The Delaware Supreme Court held, among other things, that Lesh was entitled to submit extrinsic evidence in support of his position on standing, and that the trial court on remand should allow the submission of such evidence, if any exist.

On or about November 21, 2005, a second lawsuit was filed in Delaware Superior Court relating to the acquisition of Appriva Medical, Inc. The named plaintiff is Appriva Shareholder Litigation Company, LLC, which according to the complaint was formed for the purpose of pursuing claims against us. The complaint alleges that Erik van der Burg and three unidentified institutional investors have assigned their claims as former shareholders of Appriva to Appriva Shareholder Litigation Company, LLC. The complaint alleges specified damages in the form of the second milestone payment (\$25 million), which is claimed to be due and payable, and further alleges unspecified damages to be proven at trial. The complaint alleges the following claims: misrepresentation, breach of contract, breach of the implied covenant of good faith and fair dealing and declaratory relief. We believe these allegations and claims are without merit and intend to vigorously defend this action. We filed a motion to dismiss the complaint. On August 24, 2006, the trial court converted our motion to dismiss into a motion for summary judgment, which motion was granted. The trial court ruled that Appriva Shareholder Litigation Company, LLC did not have standing. The trial court did not address the merits of the claims. Appriva Shareholder Litigation Company, LLC has appealed the trial court's ruling. The Lesh appeal and the Appriva Shareholder Litigation Company, LLC appeal were consolidated for purposes of appeal. By decision dated November 1, 2007, the Delaware Supreme Court reversed and remanded the trial court's ruling. The Delaware Supreme Court held, among other things, that Appriva Shareholder Litigation Company was entitled to submit extrinsic evidence in support of its position on standing, and that the trial court on remand should allow the submission of such evidence, if any exist. Because both of these Appriva acquisition related matters are in early stages, we cannot estimate the possible loss or range of loss, if any, associated with their resolution. However, there can be no assurance that the ultimate resolution of these matters will not result in a material adverse effect on our business, financial condition or results of operations.

## FoxHollow Litigation

As a result of our acquisition of FoxHollow, we assumed the following material legal proceedings and contingencies from FoxHollow and its subsidiaries.

In July 2006, August 2006 and February 2007, three separate shareholder class action complaints were filed against FoxHollow and two of its officers in the U.S. District Court for the Northern District of California. The plaintiffs are seeking to represent a class of purchasers of FoxHollow's common stock from May 13, 2005 to January 26, 2006. The complaints generally allege that false or misleading statements were made concerning FoxHollow's management and seek unspecified monetary damages. A motion to dismiss was granted with leave to amend on September 5, 2007, and the plaintiffs filed an amended complaint on October 19, 2007. Because these matters are in early stages and because of the complexity of the cases, we cannot estimate the possible loss or range of loss, if any, associated with their resolution. However, there can be no assurance that the ultimate resolution of these matters will not result in a material adverse effect on our business, financial condition or results of operations.

In July 2006, a shareholder derivative complaint was filed against FoxHollow's directors and certain of its officers in the Superior Court of the State of California, San Mateo County. The complaint is based on substantially similar facts and circumstances as the class action complaints described above and generally alleges that the named individuals breached their fiduciary duties to FoxHollow. The original complaint sought unspecified monetary damages. A demurrer was sustained with leave to amend on May 31, 2007. Any recovery in this derivative suit would be to the benefit of FoxHollow.

In August 2006, a shareholder derivative complaint was filed against FoxHollow's directors and certain of its officers in the U.S. District Court for the Northern District of California, San Jose division. In January

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

2007, the plaintiffs filed an amended complaint adding a former executive and directors as defendants. The complaint is based on substantially similar facts and circumstances as the class action complaints and generally alleges that the named individuals breached their fiduciary duties to the company. The complaint seeks unspecified monetary damages. A motion to dismiss has been filed in this action, as well. However, the parties recently agreed to stay all proceedings in this action until a ruling is made on the defendants' motion to dismiss in the securities class action litigation described above. Similar to the derivative litigation in the Superior Court, any recovery in this derivative suit would be to the benefit of FoxHollow.

In February 2007, David Martin, FoxHollow's former chief operating officer, filed a wrongful termination and defamation suit against FoxHollow and one of its officers in the Superior Court of the State of California, San Mateo County. In March 2007, the Superior Court granted Martin's petition to compel arbitration of his claims and arbitration is currently in its initial stages. The complaint is based on substantially similar facts and circumstances as the class action complaints and derivative actions. Martin generally alleges that he was terminated from his employment in violation of the covenant of good faith and fair dealing and in retaliation for actions he had the legal right to take. Martin seeks economic damages in excess of \$10 million, plus non-economic and exemplary damages. On May 1, 2007, the Court granted Martin's petition to compel arbitration. Because this matter is in an early stage and because of the complexity of the case, we cannot estimate the possible loss or range of loss, if any, associated with its resolution. However, there can be no assurance that the ultimate resolution of this matter will not result in a material adverse effect on our business, financial condition or results of operations.

On August 31, 2007, Scion Cardio-Vascular, Inc., a/k/a Scion CV, Inc., filed an action against FoxHollow in the Circuit Court of the Eleventh Judicial Circuit in and for Miami-Dade County, Florida. The complaint alleged breach of fiduciary duty, breach of an August 2, 2006 distribution agreement between Scion and FoxHollow concerning the Scion Sci-Pro embolic protection device, and fraud. The complaint claimed compensatory damages "in excess of \$50 million" and punitive damages. In January 2008 the parties reached a settlement pursuant to which Scion has agreed to dismiss all claims with prejudice.

## 20. Segment and Geographic Information

Our management, including our chief executive officer who is our chief operating decision maker, report and manage our operations in two reportable business segments based on similarities in the products sold, customer base and distribution system. Our peripheral vascular segment contains products that are used primarily in peripheral vascular and cardiovascular procedures by radiologists, vascular surgeons and cardiologists. Our neurovascular segment contains products that are used primarily by neuroradiologists and neurosurgeons.

Management measures segment profitability on the basis of gross profit calculated as net sales less cost of goods sold excluding amortization of intangible assets. Other operating expenses are not allocated to individual operating segments for internal decision making activities.

We sell our products through a direct sales force in the United States, Canada and Europe as well as through distributors in other international markets and in the United States. Our customers include a broad physician base consisting of vascular surgeons, neuro surgeons, other endovascular specialists, radiologists, neuroradiologists and cardiologists.

ev3 Inc.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following is segment information (in thousands):

	For the Years Ended December 31,			
	2007	2005		
Net sales				
Peripheral vascular				
Atherectomy	\$ 20,884	\$ —	\$	
Stents	86,035	64,092	37,871	
Thrombectomy and embolic protection	25,998	21,606	12,869	
Procedural support and other	40,858	35,406	29,141	
Total Peripheral vascular	173,775	121,104	79,881	
Neurovascular				
Embolic products	56,003	38,998	22,463	
Neuro access and delivery products	48,448	42,336	31,352	
Total Neurovascular	104,451	81,334	53,815	
Research collaboration	5,957		<del>·</del>	
Total net sales	\$ 284,183	\$202,438	<u>\$ 133,696</u>	
Gross profit				
Peripheral vascular	\$ 100,693	\$ 68,933	\$ 41,329	
Neurovascułar	77,654	62,184	37,273	
Research collaboration	4,892			
Total	\$ 183,239	<u>\$131,117</u>	<u>\$ 78,602</u>	
Total assets	- •			
Peripheral vascular	\$ 936,348	\$209,414		
Neurovascular	150,758	143,412		
Total	\$1,087,106	\$352,826		
Gross profit(1)	\$ 183,239	\$131,117	\$ 78,602	
Operating expense	352,762	187,675	181,448	
Loss from operations	\$ (169,523)	<u>\$ (56,558</u> )	<u>\$(102,846)</u>	

<sup>(1)</sup> Gross profit for internal measurement purposes is defined as net sales less cost of goods sold excluding amortization of intangible assets.

For the years ended December 31, 2007, 2006 and 2005, no single customer represented more than 10% of our consolidated net sales.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table presents net sales and long-lived assets by geographic area for the years ended December 31 (in thousands):

1 . *		December 31,	
Geographic Data	2007	2006	2005
Net sales			
United States		\$121,180	\$ 71,848
International	106,985	81,258	61,848
Total net sales	<u>\$284,183</u>	\$202,438	<u>\$133,696</u>
Long-lived assets			
United States		\$ 23,422	
International	970	650	
Total long-lived assets	<u>\$ 37,985</u>	<u>\$ 24,072</u>	

## 21. Related Party Transaction

During the second quarter 2007, we entered into a distribution agreement with Beijing Lepu Medical Device, Inc. ("Lepu"), a Chinese domiciled manufacturer and distributor of interventional cardiology and peripheral products. The two year agreement allows Lepu to sell certain of our embolic protection devices and stents in China. We believe that having access to Lepu and their sub-distributor network is a strategic way for us to quickly gain access and market share in these strategic markets. Warburg Pincus Equity Partners, L.P. and certain of its affiliates ("Warburg Pincus"), who collectively owned over 50% of our outstanding common stock at that time and together with Vertical Group, L.P. ("Vertical") have two designees on our board of directors, owns an approximate 20% ownership interest in Lepu and has a designee on Lepu's board of directors. For the year ended December 31, 2007, Lepu had purchased peripheral vascular products from us totaling approximately \$1.5 million that we have recognized as revenue and, as of December 31, 2007, owed us approximately \$306,000 that is included in accounts receivable.

During the third quarter 2007, we entered into a distribution agreement with Bacchus Vascular, Inc. ("Bacchus"), a provider of medical devices used by interventional radiologists and vascular surgeons for the minimally invasive treatment of deep vein thrombosis and other peripheral vascular disease. The six-year agreement allows Bacchus to sell certain of our products. We have entered into an option agreement with Bacchus, which grants ev3 a call option and Bacchus a put option to cause ev3 to acquire Bacchus at a formula price in 2010. The call and put options are terminable by either party prior to December 31, 2009. Warburg Pincus and Vertical and certain of their affiliates, who collectively owned over 56% of our outstanding common stock at that time and who have two designees on our board of directors, own an approximate 64% ownership interest in Bacchus and have designees on Bacchus' board of directors. For the year ended December 31, 2007, Bacchus had purchased peripheral vascular products from us totaling approximately \$486,000 that we have recognized as revenue and, as of December 31, 2007, owed us approximately \$182,000 that is included in accounts receivable.

As a result of our acquisition of FoxHollow, we assumed the obligations of FoxHollow under a time-sharing agreement, effective as of September 1, 2005, between FoxHollow and JBS Consulting, LLC, an entity affiliated with John B. Simpson, Ph.D., M.D., who served as our vice chairman and chief scientist from October 4, 2007 through February 7, 2008, and a reimbursement agreement, also effective as of September 1, 2005, among FoxHollow, JBS Consulting and Dr. Simpson. Under the terms of the time-sharing agreement, FoxHollow leased an airplane owned by JBS Consulting and a flight crew in exchange for FoxHollow's payment of the aggregate incremental cost of each flight conducted at the request of FoxHollow, which costs included fuel, oil, lubricants and other additives, travel expenses of the crew, hangar and tie down costs away from the airplane's base of operation in San Jose, California, insurance for each specific flight, landing fees, airport taxes, customs, in-flight food and beverages, passenger ground transportation, flight planning and an additional charge equal to 100% of

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

fuel, oil, lubricants, and other additives. JBS Consulting then invoiced FoxHollow, net 30 days, for each flight's costs at the end of the month. Under the terms of the reimbursement agreement, after FoxHollow paid all of the invoiced costs, FoxHollow then invoiced, net 10 days, JBS Consulting and/or Dr. Simpson under the reimbursement agreement for reimbursement of all costs and expenses paid by FoxHollow for each flight's costs, except for the cost of a first class fare equivalent commercial airline ticket for all flights when Dr. Simpson was aboard the airplane in connection with FoxHollow business and for the cost of a coach fare equivalent commercial airline ticket for all flights when any FoxHollow employee or director was aboard the airplane in connection with FoxHollow business. We terminated the time-sharing agreement and reimbursement agreement after Dr. Simpson's resignation in February 2008.

#### 22. Loss Per Share

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The following outstanding options were excluded from the computation of diluted loss per share as they had an antidilutive effect:

		Year	Year Ended December 31,		
		2007	2006	2005	
	Options	<u>12,051,561</u>	5,359,248	3,638,309	
3.	Quarterly Financial Data (Unaudited)				
		Loss from Operations	Net Loss	Loss per Share	

	Net Sales			oss from perations		Net Loss		Loss per Share
2007								
First Quarter	\$61,499		\$	(9,644)		\$ (9,494)		\$(0.17)
Second Quarter	65,396			(12,031)		(11,871)		(0.20)
Third Quarter	65,060			(38,233)	(1)	(36,512)	(1)	(0.60)
Fourth Quarter	92,228	(2)	(	109,615)	(3)	(107,867)	(3)	(1.06)
2006								
First Quarter	\$42,237		\$	(25,085)	(4)	\$ (24,501)	(4)	\$(0.44)
Second Quarter	50,620			(13,650)		(10,823)		(0.19)
Third Quarter	51,906			(12,795)		(12,467)		(0.22)
Fourth Quarter	57,675			(5,028)		(4,580)		(80.0)

- (1) In third quarter of 2007, we incurred special charges of \$19.1 million as a result of us entering into agreements in principle to settle certain patent infringement and other litigation with The Regents of the University of California and Boston Scientific Corporation. For additional discussion see Note 19 above.
- (2) In October 2007, we completed our acquisition of FoxHollow, which broadened our peripheral vascular product offering to include atherectomy and additional thrombectomy products, including the SilverHawk Plaque Excision System. Our fourth quarter net sales included \$20.9 million of net sales from FoxHollow products. As a result of our FoxHollow acquisition, we also now recognize research collaboration revenue from our collaboration and license agreement with Merck. Research collaboration revenue for fourth quarter 2007 was \$6.0 million.
- (3) In the fourth quarter of 2007, we recorded a charge of \$70.7 million for acquired in-process research and development as a result of the acquisition of FoxHollow on October 4, 2007. For additional discussion see Note 4 above. We also made approximately \$3.3 million of adjustments in our excess and obsolete inventory reserves for the planned discontinuance of the Primus balloon expandable stent and the Sailor .035 balloon due to our strategic marketing focus on new product introductions.
- (4) In the first quarter of 2006, we recorded a charge of \$1.8 million for acquired in-process research and development related to our acquisition of MTI on January 6, 2006 and \$4.4 million of litigation and business development charges.

ev3 Inc.
Schedule II
Valuation and Qualifying Accounts

Description	Balance at Beginning Period	Charged to Revenue, Costs or Expenses	Other Additions	Deductions	Balance at End of Period
Reserves deducted from assets to which it applies:					
Year ended December 31, 2007	•				
Reserve for deferred income tax asset	\$191,960	\$34,273	\$ <b>—</b>	\$(27,193)(b)	\$199,040
Accounts receivable allowances	3,924	2,024	1,661 (a)	(826)	6,783
Reserve for inventory obsolescence	4,725	9,018	1,513 (a)	(4,288)	10,968
Year ended December 31, 2006					
Reserve for deferred income tax asset	\$176,142	\$15,818	\$ <del></del>	\$ —	\$191,960
Accounts receivable allowances	3,607	746		(429)	3,924
Reserve for inventory obsolescence	3,975	3,725		(2,975)	4,725
Year ended December 31, 2005					
Reserve for deferred income tax asset	\$144,261	\$31,881	\$ <b>—</b>	\$ <del>-</del>	\$176,142
Accounts receivable allowances	2,694	1,110	<del></del>	(197)	3,607
Reserve for inventory obsolescence	3,687	4,037	_	(3,749)	3,975

<sup>(</sup>a) Other additions primarily related to acquisitions.

<sup>(</sup>b) Other deductions primarily related to acquisitions.

# ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## ITEM 9A. CONTROLS AND PROCEDURES

## **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) that are designed to reasonably ensure that information required to be disclosed by us in the reports we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated can provide only reasonable assurance of achieving the desired control objectives and we necessarily are required to apply our judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered in this annual report on Form 10-K. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of the end of such period to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that material information relating to our company and our consolidated subsidiaries is made known to management, including our Chief Executive Officer and Chief Financial Officer, particularly during the period when our periodic reports are being prepared.

## Management's Report on Internal Control Over Financial Reporting

Our management report on internal control over financial reporting is included in this report in Item 8, under the caption "Management's Report on Internal Control over Financial Reporting." On October 4, 2007, we completed our acquisition of FoxHollow Technologies, Inc. Our management's assessment of and conclusion on the effectiveness of our internal control over financial reporting did not include the internal controls of FoxHollow Technologies, Inc. as of December 31, 2007 because it was acquired by us in a purchase business combination during fiscal 2007. FoxHollow Technologies, Inc. is a wholly-owned subsidiary of ours included in our consolidated financial statements and constituted less than 10 percent of our total assets at December 31, 2007, approximately 10 percent of our revenue and approximately 12 percent of our net loss for the year then ended.

The report of Ernst & Young LLP, our independent registered public accounting firm, regarding the effectiveness of our internal control over financial reporting is included in this report in Item 8, under the heading "Report of Independent Registered Public Accounting Firm." Ernst & Young LLP's audit of internal control over financial reporting of ev3 Inc. also did not include an evaluation of the internal control over financial reporting of FoxHollow Technologies, Inc.

## Change in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during our fourth quarter ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## ITEM 9B. OTHER INFORMATION

Not applicable.

### PART III

## ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

## **Directors**

The information in the "Proposal One — Election of Directors" section of our proxy statement in connection with our 2008 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

## **Executive Officers**

Information about our executive officers is included in this annual report on Form 10-K under Item 4A, "Executive Officers of the Registrant."

## Section 16(a) Beneficial Ownership Reporting Compliance

The information in the "Stock Ownership — Section 16(a) Beneficial Ownership Reporting Compliance" section of our proxy statement in connection with our 2008 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

## Code of Conduct and Ethics

The information in the "Corporate Governance — Code of Conduct and Ethics" section of our proxy statement in connection with our 2008 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

# **Changes to Nomination Procedures**

We have made no material changes to the procedures by which stockholders may recommend nominees to our board of directors, as described in our most recent proxy statement.

## **Audit Committee Matters**

The information under the heading "Corporate Governance — Audit Committee" section of our proxy statement in connection with our 2008 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

## ITEM 11. EXECUTIVE COMPENSATION

The information in the "Compensation Discussion & Analysis," the "Executive Compensation" and the "Director Compensation" sections of our proxy statement in connection with our 2008 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

# ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

# Securities Authorized for Issuance Under Equity Compensation Plans

The following table and notes provide information about shares of our common stock that may be issued under all of our equity compensation plans as of December 31, 2007.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b)  Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	(c)  Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Equity compensation plans approved by security holders	6,995,711(1)(2)	12.17(3)	5,759,678(4)
Equity compensation plans not approved by security holders	0(5)(6)	N/A 12.17	0 5,759,678

- (1) Amount includes shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2007 under the ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan and the ev3 LLC Amended and Restated 2003 Incentive Plan and shares of our common stock issuable upon the vesting of restricted stock units outstanding as of December 31, 2007 under the ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan.
- (2) Excludes employee stock purchase rights accruing under the ev3 Inc. Employee Stock Purchase Plan. Under such plan, each eligible employee may purchase up to 2,500 shares of our common stock at semi-annual intervals on June 30th and December 31st each year at a purchase price per share equal to 85% of the lower of (i) the closing sales price per share of our common stock on the first day of the offering period or (ii) the closing sales price per share of our common stock on the last day of the offering period.
- (3) Included in the weighted-average exercise price calculation are 1,177,334 restricted stock units with an exercise price of \$0.00. The weighted-average exercise price of all outstanding stock options as of December 31, 2007 and reflected in column (a) was \$14.62.
- (4) Amount includes 5,070,212 shares remaining available at December 31, 2007 for future issuance under the ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan and 689,466 shares remaining available at December 31, 2007 for future issuance under the ev3 Inc. Employee Stock Purchase Plan. No shares remain available for grant under the ev3 LLC Amended and Restated 2003 Incentive Plan since such plan was terminated with respect to future grants in June 2005.
- (5) Excludes options assumed by us in connection with our acquisitions of Micro Therapeutics, Inc. and FoxHollow Technologies, Inc. As of December 31, 2007, a total of 6,233,184 shares of our common stock were issuable upon exercise of the assumed options. The weighted average exercise price of the outstanding assumed options as of such date was \$14.73 per share and they have an average weighted life remaining of 7.84 years. 946,638 of the 1,057,646 options outstanding in connection with our acquisition of Micro Therapeutics, Inc. were exercisable as of December 31, 2007. 3,136,631 of the 5,291,169 options assumed and outstanding in connection with our acquisition of FoxHollow Technologies, Inc. were exercisable as of December 31, 2007. No additional options, restricted stock units or other equity incentive awards may be granted under the assumed Micro Therapeutics, Inc. and FoxHollow Technologies, Inc. plans.
- (6) Excludes shares issuable upon the vesting of restricted stock units assumed by us in connection with our acquisition of FoxHollow Technologies, Inc. As of December 31, 2007, a total of 115,631 shares of our common stock were issuable upon the vesting of the assumed restricted stock units.

## Stock Ownership

The information in the "Stock Ownership" section of our proxy statement in connection with our 2008 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

# ITEM 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information in the "Related Person Relationships and Transactions," the "Proposal One — Election of Directors — Information about Board Nominees and Other Directors," the "Proposal One — Election of Directors — Additional Information about Board Nominees and Other Directors," and "Corporate Governance — Director Independence" section of our proxy statement in connection with our 2008 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

#### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information in the "Proposal Two — Ratification of Selection of Independent Registered Public Accounting Firm — Audit, Audit-Related, Tax and Other Fees" and the "Proposal Two — Ratification of Selection of Independent Registered Public Accounting Firm — Pre-Approval Policies and Procedures" sections of our proxy statement in connection with our 2008 annual meeting of stockholders to be filed with the Securities and Exchange Commission is incorporated in this annual report on Form 10-K by reference.

#### PART IV

## ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Our consolidated financial statements are included in Item 8 of Part II of this report.

The following financial statement schedule is included in Item 8 of Part II of this report: Schedule II — Valuation and Qualifying Accounts. All other schedules are omitted because the required information is inapplicable or the information is presented in the consolidated financial statements or related notes.

The exhibits to this report are listed on the Exhibit Index on pages 96 to 102. A copy of any of the exhibits listed or referred to above will be furnished at a reasonable cost, upon receipt from any such person of a written request for any such exhibit. Such request should be sent to ev3 Inc., 9600 54<sup>th</sup> Avenue North, Suite 100, Plymouth, Minnesota 55442, Attn: Stockholder Information.

The following is a list of each management contract or compensatory plan or arrangement required to be filed as an exhibit to this annual report on Form 10-K pursuant to Item 13(a):

- A. Employee Confidentiality/Restrictive Covenant Agreement, dated as of May 20, 2003, between ev3 Endovascular, Inc. (formerly known as ev3 Inc.) and James M. Corbett (incorporated by reference to Exhibit 10.4 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)).
- B. Employee Confidentiality/Restrictive Covenant Agreement, dated as of March 21, 2005, between ev3 Endovascular, Inc. and Patrick D. Spangler (incorporated by reference to Exhibit 10.6 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)).
- C. Offer Letter, dated as of March 31, 2005, between ev3 LLC, ev3 Inc. and Patrick D. Spangler (incorporated by reference to Exhibit 10.53 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)).

- D. Offer Letter, dated April 3, 2006, between ev3 Inc. and Matthew Jenusaitis (incorporated by reference to Exhibit 10.4 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 2, 2006 (File No. 000-51348)).
- E. Employment Agreement, dated April 3, 2006, between ev3 Inc. and Matthew Jenusaitis (incorporated by reference to Exhibit 10.4 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 2, 2006 (File No. 000-51348)).
- F. Consulting Agreement, dated as of November 22, 2004, by and between ev3 Endovascular, Inc. (formerly known as ev3 Inc.) and Dale A. Spencer (incorporated by reference to Exhibit 10.10 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)).
- G. Change in Control Agreement, dated September 19, 2006, among ev3 Inc., ev3 Endovascular, Inc. and James M. Corbett (incorporated by reference to Exhibit 10.2 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended October 1, 2006 (File No. 000-51348)).
- H. Change in Control Agreement, dated September 19, 2006, among ev3 Inc., ev3 Endovascular, Inc. and Dale A. Spencer (incorporated by reference to Exhibit 10.1 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended October 1, 2006 (File No. 000-51348)).
- I. Form of Change in Control Agreement among ev3 Inc., ev3 Endovascular, Inc. or Micro Therapeutics, Inc. and each of its executive officers (incorporated by reference to Exhibit 10.3 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended October 1, 2006 (File No. 000-51348)).
- J. Change in Control and Severance Agreement, dated April 9, 2007, by and between John B. Simpson, Ph.D., M.D. and FoxHollow Technologies, Inc. (filed herewith).
- K. Time-Sharing Agreement dated September 1, 2005, by and between FoxHollow Technologies, Inc. and JBS Consulting, LLC (incorporated by reference to Exhibit 10.16 to FoxHollow's Annual Report on Form 10-K for the year ended December 31, 2005 (File No. 000-50998)).
- L. Reimbursement Agreement dated September 1, 2005, by and among FoxHollow Technologies, Inc., John B. Simpson, and JBS Consulting, LLC (incorporated by reference to Exhibit 10.17 to FoxHollow's Annual Report on Form 10-K for the year ended December 31, 2005 (File No. 000-50998)).
- M. Form of Indemnification Agreement for directors and officers of ev3 Inc. (incorporated by reference to Exhibit 10.15 to ev3's Amendment No. 4 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 2, 2005 (File No. 333-123851)).
- N. ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan (incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 17, 2007 (File No. 000-51348)).
- O. Form of Non-Statutory Stock Option Grant Certificate under ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan (incorporated by reference to Exhibit 10.2 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 26, 2007 (File No. 000-51348)).
- P. Form of Stock Grant Certificate under ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan (incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 26, 2007 (File No. 000-51348)).
- Q. Form of Stock Grant Certificate under ev3 Inc. Amended and Restated 2005 Incentive Stock Plan applicable to French Participants (incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 31, 2006 (File No. 000-51348)).
- R. ev3 LLC Amended and Restated 2003 Incentive Plan (incorporated by reference to Exhibit 10.2 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 2, 2006 (File No. 000-51348)).

- S. Micro Therapeutics, Inc. 1996 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.7.1 to Micro Therapeutics, Inc.'s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002 (File No. 000-06523)).
- T. Micro Therapeutics, Inc. 1993 Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan (incorporated by reference to Exhibit 10.6 to Micro Therapeutics, Inc.'s Registration Statement on Form SB-2 filed with the Securities and Exchange Commission on December 5, 1996 (File No. 333-17345)).
- U. ev3 Inc. Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.24 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2005 (File No. 000-51348)).
  - V. ev3 Inc. Executive Performance Incentive Plan (filed herewith)
- W. FoxHollow Technologies, Inc. 2004 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to FoxHollow's Amendment No. 2 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 13, 2004 (Registration No. 333-118191))
- X. FoxHollow Technologies, Inc. 1997 Stock Plan (incorporated by reference to Exhibit 10.2 to FoxHollow's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 13, 2004 (Registration No. 333-118191))

# **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

# ev3 INC.

Dated: March 13, 2008	Ву/	s/ JAMES M. CORBETT
		James M. Corbett resident and Chief Executive Office. principal executive officer)
	τ,	
	By/s.	PATRICK D. SPANGLER
		Patrick D. Spangler President and Chief Financial Officer l financing and accounting officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name and Signature	Title	Date
James M. Corbett  James M. Corbett	Chairman, President and Chief Executive Officer	March 13, 2008
John K. Bakewell	Director	March 13, 2008
/s/ JEFFREY B. CHILD  Jeffrey B. Child	Director	March 13, 2008
/s/ RICHARD B. EMMITT Richard B. Emmitt	Director	March 13, 2008
/s/ RICHARD N. KENDER Richard N. Kender	Director	March 13, 2008
/s/ Daniel J. Levangie Daniel J. Levangie	Director	March 13, 2008
/s/ Myrtle S, Potter  Myrtle S, Potter	Director	March 13, 2008
/s/ THOMAS E. TIMBIE Thomas E. Timbie	Director	March 13, 2008
/s/ ELIZABETH H. WEATHERMAN Elizabeth H. Weatherman	Director	March 13, 2008

# ev3 INC.

# EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K For the Year Ended December 31, 2007

Exhibit No.	Exhibit	Method of Filing
2.1	Agreement and Plan of Merger, dated as of April 4, 2005, by and between ev3 LLC and ev3 Inc.	Incorporated by reference to Exhibit 2.1 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
2.2	Contribution and Exchange Agreement, dated as of April 4, 2005, by and among the institutional stockholders listed on Schedule I thereto, ev3 LLC, ev3 Inc. and Micro Therapeutics, Inc.	Incorporated by reference to Exhibit 2.2 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
2.3	Note Contribution and Exchange Agreement, dated as of April 4, 2005, by and among the noteholders listed on Schedule I thereto and ev3 Inc.	Incorporated by reference to Exhibit 2.3 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
2.4	Agreement and Plan of Merger, dated as of July 15, 2002, by and among Microvena Corporation, Appriva Acquisition Corp. and Appriva Medical, Inc.	Incorporated by reference to Exhibit 2.4 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
2.5	Asset Purchase Agreement, dated as of September 29, 2004, among Edwards Lifesciences AG and ev3 Santa Rosa, Inc., ev3 Technologies, Inc. and ev3 Endovascular, Inc. (formerly known as ev3 Inc.)(1)	Incorporated by reference to Exhibit 2.5 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
2.6	Stock Purchase Agreement, dated September'3, 2002, by and between Micro Therapeutics, Inc. and the holders of the outstanding equity securities of Dendron	Incorporated by reference to Exhibit 2.2 to Micro Therapeutics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 10, 2002 (File No. 000-06523)
2.7	Agreement and Plan of Merger, dated November 14, 2005, by and between ev3 Inc., Micro Investment, LLC and Micro Therapeutics, Inc.	Incorporated by reference to Exhibit 2.1 to ev3's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 14, 2005 (File No. 000-51348)
2.8	Agreement and Plan of Merger dated as of July 21, 2007 by and among ev3 Inc., Foreigner Merger Sub, Inc. and FoxHollow Technologies, Inc.(2)	Incorporated by reference to Exhibit 2.1 to ev3's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 23, 2007 (File No. 000-51348)
2.9	Agreement and Plan of Merger, dated as of August 26, 2006, by and between FoxHollow Technologies, Inc. and Kerberos Proximal Solutions, Inc.	Incorporated by reference to Exhibit 2.1 to FoxHollow's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 28, 2006 (File No. 000-50998)
3.1	Amended and Restated Certificate of Incorporation of ev3 Inc.	Incorporated by reference to Exhibit 3.1 to ev3's Amendment No. 5 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 14, 2005 (File No. 333-123851)
3.2	Amendment to Amended and Restated Certificate of Incorporation of ev3 Inc.	Incorporated by reference to Exhibit 99.1 to ev3's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 27, 2005 (File No. 000-51348)

Exhibit No.	Exhibit	Method of Filing
3.3	Amendment to Amended and Restated Certificate of Incorporation of ev3 Inc.	Incorporated by reference to Exhibit 3.1 to ev3's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 23, 2007 (File No. 000-51348)
3.4	Amended and Restated Bylaws of ev3 Inc.	Incorporated by reference to Exhibit 3.3 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 3, 2005 (File No. 000-51348)
4.1	Form of Stock Certificate	Incorporated by reference to Exhibit 4.1 to ev3's Amendment No. 4 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 2, 2005 (File No. 333-123851)
4.2	Holders Agreement, dated as of August 29, 2003, among the institutional investors listed on Schedule I thereto, Dale A. Spencer, Paul Buckman, the individuals whose names and addresses appear from time to time on Schedule II thereto, the individuals whose names and addresses appear from time to time on Schedule III thereto and ev3 LLC	Incorporated by reference to Exhibit 4.2 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
4.3	Operating Agreement of ev3 LLC, dated as of August 29, 2003, by and among ev3 LLC, Warburg, Pincus Equity Partners, L.P., Warburg, Pincus Netherlands Equity Partners I, C.V., Warburg, Pincus Netherlands Equity Partners II, C.V., Warburg, Pincus Netherlands Equity Partners III, C.V., Vertical Fund I, L.P., Vertical Fund II, L.P. and certain other persons party thereto	Incorporated by reference to Exhibit 4.3 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
4.4	Amendment No. 1 to Operating Agreement of ev3 LLC, dated as of March 1, 2005, by and among ev3 LLC, Warburg, Pincus Equity Partners, L.P., Warburg, Pincus Netherlands Equity Partners I, C.V., Warburg, Pincus Netherlands Equity Partners II, C.V., Warburg, Pincus Netherlands Equity Partners III, C.V., Vertical Fund I, L.P., Vertical Fund II, L.P. and certain other persons party thereto	Incorporated by reference to Exhibit 4.4 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
4.5	Registration Rights Agreement, dated as of June 21, 2005, by and among ev3 Inc., Warburg, Pincus Equity Partners, L.P., Warburg, Pincus Netherlands Equity Partners I, C.V., Warburg, Pincus Netherlands Equity Partners II, C.V., Warburg, Pincus Netherlands Equity Partners III, C.V., Vertical Fund I, L.P., Vertical Fund II, L.P., and certain other investors party thereto	Incorporated by reference to Exhibit 4.2 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 3, 2005 (File No. 000-51348)
4.6	Stock Purchase Agreement, dated as of September 26, 2006, between FoxHollow Technologies, Inc. and Merck & Co., Inc.	Incorporated by reference to Exhibit 4.3 to FoxHollow's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 28, 2006 (File No. 000-50998)

Exhibit No.	<u>Exhibit</u>	Method of Filing
10.1	Lease Agreement, dated May 3, 2002, by and between Liberty Property Limited Partnership and ev3 Endovascular, Inc. (formerly known as ev3 Inc.)	Incorporated by reference to Exhibit 10.1 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
10.2	First Amendment to the May 3, 2002 Lease Agreement between Liberty Property Limited Partnership and ev3 Endovascular, Inc. (formerly known as ev3 Inc.), effective as of October 17, 2005	Incorporated by reference to Exhibit 10.2 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 (File No. 000-51348)
10.3	Second Amendment to the May 3, 2002 Lease Agreement between Liberty Property Limited Partnership and ev3 Endovascular, Inc. (formerly known as ev3 Inc.), effective as of October 1, 2005	Incorporated by reference to Exhibit 10.3 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 (File No. 000-51348)
10.4	Lease Agreement dated August 30, 2005 between Liberty Property Limited Partnership and ev3 Inc.	Incorporated by reference to Exhibit 10.2 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended October 2, 2005 (File No. 000-51348)
10.5	First Amendment to the August 30, 2005 Lease Agreement between Liberty Property Limited Partnership and ev3 Inc., effective as of April 6, 2006	Incorporated by reference to Exhibit 10.5 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 (File No. 000-51348)
10.6	Second Amendment to the August 30, 2005 Lease Agreement, between Liberty Property Limited Partnership and ev3 Inc., effective as of February 8, 2007	Incorporated by reference to Exhibit 10.6 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 (File No. 000-51348)
10.7	Lease, dated October 13, 2005, by and between Micro Therapeutics, Inc. and The Irvine Company	Incorporated by reference to Exhibit 10.53 to Micro Therapeutics, Inc.'s Current Report on Form' 8-K filed with the Securities and Exchange Commission on October 18, 2005 (File No. 000-06523)
10.8	Office Building Lease, dated May 3, 2004, by and between FoxHollow Technologies, Inc. and Woodside Technology Center, LLC for office space located at 740 Bay Road, Redwood City, California	Incorporated by reference to Exhibit 10.10 to FoxHollow's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 13, 2004 (Registration No. 333-118191)
10.9	Office Building Lease, dated November 3, 2006, by and between FoxHollow Technologies, Inc. and Slough Redwood City, LLC, for office space located at 900 Chesapeake Drive, Redwood City, California	Incorporated by reference to Exhibit 10.23 to FoxHollow's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 14, 2006 (File No. 000-50998)
10.10	Office Building Lease, dated January 5, 2007, by and between FoxHollow Technologies, Inc. and AMB Property, L.P., for office space located at 1105 Hamilton Court, Menlo Park, California	Incorporated by reference to Exhibit 10.26 to FoxHollow's Annual Report on Form 10-K for the year ended December 31, 2006 (File No. 000-50998)
10.11	Employee Confidentiality/Restrictive Covenant Agreement, dated as of May 20, 2003, between ev3 Endovascular, Inc. (formerly known as ev3 Inc.) and James M. Corbett	Incorporated by reference to Exhibit 10.4 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)

Exhibit No.	Exhibit	Method of Filing
10.12	Employee Confidentiality/Restrictive Covenant Agreement, dated as of March 21, 2005, between ev3 Endovascular, Inc. and Patrick D. Spangler	Incorporated by reference to Exhibit 10.6 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
10.13	Employment Offer Letter, dated as of March 31, 2005, between ev3 LLC, ev3 Inc. and Patrick D. Spangler	Incorporated by reference to Exhibit 10.53 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
10.14	Offer Letter, dated April 3, 2006, between ev3 Inc. and Matthew Jenusaitis	Incorporated by reference to Exhibit 10.4 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 2, 2006 (File No. 000-51348)
10.15	Employment Agreement, dated April 3, 2006, between ev3 Inc. and Matthew Jenusaitis	Incorporated by reference to Exhibit 10.5 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 2, 2006 (File No. 000-51348)
10.16	Consulting Agreement, dated as of November 22, 2004, by and between ev3 Endovascular, Inc. (formerly known as ev3 Inc.) and Dale A. Spencer	Incorporated by reference to Exhibit 10.10 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
10.17	Change in Control Agreement, dated September 19, 2006, among ev3 Inc., ev3 Endovascular, Inc. and James M. Corbett	Incorporated by reference to Exhibit 10.2 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended October 1, 2006 (File No. 000-51348)
10.18	Change in Control Agreement, dated September 19, 2006, among ev3 Inc., ev3 Endovascular, Inc. and Dale A. Spencer	Incorporated by reference to Exhibit 10.1 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended October 1, 2006 (File No. 000-51348)
10.19	Change in Control and Severance Agreement, dated April 9, 2007, by and between John B. Simpson, Ph.D., M.D. and Fox Hollow Technologies, Inc.	Filed herewith
10.20	Form of Change in Control Agreement among ev3 Inc., ev3 Endovascular, Inc. or Micro Therapeutics, Inc. and each of its executive officers	Incorporated by reference to Exhibit 10.3 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended October 1, 2006 (File No. 000-51348)
10.21	Form of Indemnification Agreement for directors and officers of ev3 Inc.	Incorporated by reference to Exhibit 10.15 to ev3's Amendment No. 4 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on June 2, 2005 (File No. 333-123851)
10.22	ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan	Incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 17, 2007 (File No. 000-51348)
10.23	Form of ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan Option Certificate	Incorporated by reference to Exhibit 10.2 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 26, 2007 (File No. 000-51348)

Exhibit No.	Exhibit	· Method of Filing
10.24	Form of Stock Grant Certificate under ev3 Inc. Second Amended and Restated 2005 Incentive Stock Plan	Incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 26, 2007 (File No. 000-51348)
10.25	Form of Stock Grant Notice under ev3 Inc. Amended and Restated 2005 Incentive Stock Plan applicable to French Participants	Incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 31, 2006 (File No. 000-51348)
10.26	ev3 LLC Amended and Restated 2003 Incentive Plan, as amended	Incorporated by reference to Exhibit 10.2 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 2, 2006 (File No. 000-51348)
10.27	Micro Therapeutics, Inc. 1996 Stock Incentive Plan, as amended	Incorporated by reference to Exhibit 10.7.1 to Micro Therapeutics, Inc.'s Annual Report on Form 10-KSB for the fiscal year ended December 31, 2002 (File No. 000-06523)
10.28	Micro Therapeutics, Inc. 1993 Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan	Incorporated by reference to Exhibit 10.6 to Micro Therapeutics, Inc.'s Registration Statement on Form SB-2 filed with the Securities and Exchange Commission on December 5, 1996 (File No. 333-17345)
10.29	ev3 Inc. Employee Stock Purchase Plan	Incorporated by reference to Exhibit 10.24 to ev3's Annual Report on Form 10-K for the fiscal year ended December 31, 2005 (File No. 000-51348)
10.30	ev3 Inc. Executive Performance Incentive Plan	Filed herewith
10.31	FoxHollow Technologies, Inc. 2004 Equity Incentive Plan	Incorporated by reference to Exhibit 10.3 to FoxHollow's Amendment No. 2 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on October 13, 2004 (Registration No. 333-118191)
10.32	Form of FoxHollow Technologies, Inc. 2004 Equity Incentive Plan Stock Option Award Agreement	Incorporated by reference to Exhibit 99.4 to John B. Simpson's Schedule 13D filed with the Securities and Exchange Commission on October 15, 2007 (File No. 005-80819)
10.33	FoxHollow Technologies, Inc. 1997 Stock Plan	Incorporated by reference to Exhibit 10.2 to FoxHollow's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 13, 2004 (Registration No. 333-118191)
10.34	Form of Subscription Agreement between ev3 Endovascular, Inc. (formerly known as ev3 Inc.) and Warburg, Pincus Equity Partners, L.P., Warburg, Pincus Netherlands Equity Partners I, C.V., Warburg, Pincus Netherlands Equity Partners II, C.V., Warburg, Pincus Netherlands Equity Partners III, C.V., Vertical Fund I, L.P., Vertical Fund II, L.P.	Incorporated by reference to Exhibit 10.33 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
10.35	Distribution Agreement between Invatec Technology Center GMBH and ev3 Endovascular, Inc. dated February 15, 2007(1)	Incorporated by reference to Exhibit 10.2 to ev3's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 20, 2007 (File No. 000-51348)

Exhibit No.	Exhibit	Method of Filing
10.36	Loan and Security Agreement, dated as of June 28, 2006, among Silicon Valley Bank, ev3 Endovascular, Inc., ev3 International, Inc. and Micro Therapeutics, Inc.	Incorporated by reference to Exhibit 10.8 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 2, 2006 (File No. 000-51348)
10.37	First Amendment to Loan and Security Agreement between Silicon Valley Bank and ev3 Endovascular, Inc., ev3 International, Inc. and Micro Therapeutics, Inc. dated March 15, 2007	Incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 21, 2007 (File No. 000-51348)
10.38	Consent and Second Amendment to Loan and Security Agreement between Silicon Valley Bank and ev3 Endovascular, Inc., ev3 International, Inc. and Micro Therapeutics, Inc. dated October 4, 2007	Filed herewith
10.39	Third Amendment to Loan and Security Agreement between Silicon Valley Bank and ev3 Endovascular, Inc., ev3 International, Inc. and Micro Therapeutics, Inc. dated November 2, 2007	Filed herewith :
10.40	Assumption Agreement and Fourth Amendment to Loan and Security Agreement between Silicon Valley Bank and ev3 Endovascular, Inc., ev3 International, Inc., Micro Therapeutics, Inc., and FoxHollow Technologies, Inc. dated December 14, 2007	Filed herewith
10.41	Corporate Opportunity Agreement, dated as of April 4, 2005, by and between the institutional stockholders listed on Schedule I thereto and ev3 Inc.	Incorporated by reference to Exhibit 10.32 to ev3's Registration Statement on Form S-1 filed with the Securities and Exchange Commission on April 5, 2005 (File No. 333-123851)
10.42	Underwriting Agreement dated April 19, 2007 among ev3 Inc., the Selling Stockholders listed on Schedule B thereto and Banc of America Securities LLC, Piper Jaffray & Co., JP Morgan Securities Inc., as Representatives of the Several Underwriters	Incorporated by reference to Exhibit 10.1 to ev3's Quarterly Report on Form 10-Q for the fiscal quarter ended July 1, 2007 (File No. 000-51348)
10.43	Intellectual Property Transfer Agreement dated as of June 15, 2007 between Atritech, Inc. and ev3 Endovascular, Inc.	Incorporated by reference to Exhibit 10.1 to ev3's Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 21, 2007 (File No. 000-51348)
10.44	Amended and Restated Collaboration and License Agreement, dated as of September 26, 2006, by and between FoxHollow Technologies, Inc. and Merck & Co., Inc.(1)	Incorporated by reference to Exhibit 10.22 to FoxHollow's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006 (File No. 000-50998)
10.45	Amendment, Waiver, Consent and Assumption Agreement dated as of July 21, 2007 by and among Merck & Co., Inc., FoxHollow Technologies, Inc. and ev3 Inc.	Incorporated by reference to Exhibit 10.3 to ev3's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007 (File No. 000-51348)
21.1	Subsidiaries of ev3 Inc.	Filed herewith
23.1	Consent of Ernst & Young LLP	Filed herewith
23.2	Consent of PricewaterhouseCoopers LLP	Filed herewith
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith

Exhibit No.	Exhibit	Method of Filing
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 and SEC Rule 13a-14(a)	Filed herewith
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
32.2	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith

<sup>(1)</sup> Confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended, has been granted with respect to designated portions of this document.

<sup>(2)</sup> All exhibits and schedules to the Agreement and Plan of Merger have been omitted pursuant to Item 601(b)(2) of Regulation S-K. ev3 will furnish the omitted exhibits and schedules to the Securities and Exchange Commission upon request by the Commission.

# CORPORATE INFORMATION

## BOARD OF DIRECTORS

Daniel J. Levangie Chairman of the Board

John K. Bakewell Director

Jeffrey B. Child Director

Richard B. Emmitt Director

Richard N. Kender Director

Robert J. Palmisano Director

Myrtle S. Potter Director

Thomas E. Timbie Director

Elizabeth H. Weatherman Director

# **EXECUTIVE OFFICERS**

Robert J. Palmisano President and Chief Executive Officer

Patrick D. Spangler Senior Vice President and Chief Financial Officer

Stacy Enxing Seng Senior Vice President and President, Peripheral Vascular and FoxHollow Technologies Divisions

Pascal E.R. Girin Senior Vice President and President, International

Matthew M. Jenusaitis Senior Vice President and President, Neurovascular Division

Kevin M. Klemz Senior Vice President, Secretary and Chief Legal Officer

P. Richard Lunsford Senior Vice President and President, U.S. Commercial Operations

Gregory Morrison Senior Vice President, Human Resources

David H. Mowry Senior Vice President, Corporate Manufacturing

Julie D. Tracy Senior Vice President, Chief Communications Officer

# CORPORATE HEADQUARTERS

ev3 Inc. 9600 54th Avenue North Plymouth, MN 55442 763.398.7000

## CORPORATE COUNSEL

Oppenheimer Wolff & Donnelly LLP Minneapolis, MN

# INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young LLP Minneapolis, MN

### TRANSFER AGENT

Wells Fargo Shareowner Services 161 North Concord Exchange South St. Paul, MN 55075 651.450.4000

### INVESTOR RELATIONS

ev3 Inc. 9600 54th Avenue North Plymouth, MN 55442 949.680.1375

## STOCK LISTING

ev3 is traded on the NASDAQ Global Select Market under EVVV.

## ANNUAL MEETING

May 20, 2008 2:00 p.m. (CDT) ev3 Inc. 9600 54th Avenue North Plymouth, MN 55442 763.398.7000



# ev3 Corporate World Headguarters

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# Recipheral Vascular Divisions

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# Neurovascular Division

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# Europe Headquarters

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